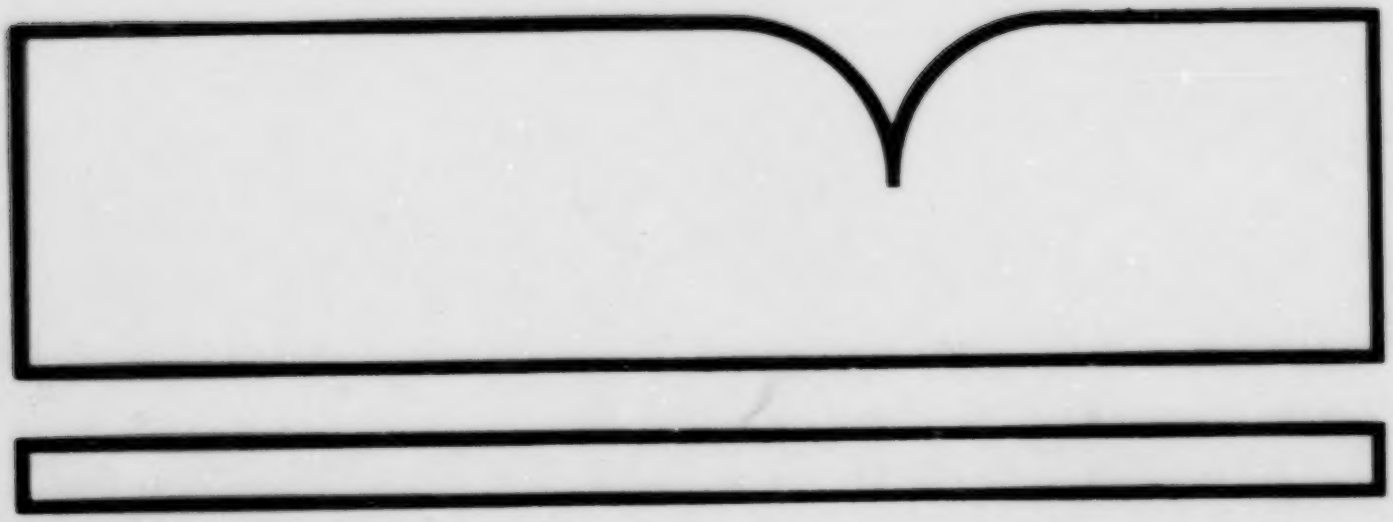
PB85-120186

Terbacil - Registration Standard

(U.S.) Environmental Protection Agency
Washington, DC

May 82



U.S. Department of Commerce
National Technical Information Service
NTIS

PORT DOCUMENTATION PAGE	1. REPORT NO.	2.	PB85-120186

4. Title and Subtitle Terbacil - Registration Standard	5. Report Date Issued 5/82 6.
7. Author(s) US. EPA, OPP, Registration Division	8. Performing Organization Rept. No. 540/RS-82-013
9. Performing Organization Name and Address USEPA, Office of Pesticide Programs Registration Division, TS-767 401 M. St. SW Wash. DC 20460	10. Project/Task/Work Unit No. 11. Contract(C) or Grant(G) No. (C) (G)
12. Sponsoring Organization Name and Address same as #9	13. Type of Report & Period Covered 14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manufacturing, chemistry, toxicology, residues, ecology, path of pollutants

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages 86
	20. Security Class (This Page)	22. Price

TABLE OF CONTENTS

Chapter		Page
I.	How to Register Under a Registration Standard	I-1
II.	Agency Position on Terbacil	
	A. Introduction	II-1
	B. Description of Chemical	II-1
	C. Regulatory Position for Manufacturing-use Products Containing Terbacil	II-2
	D. Regulatory Rationale	II-2
	E. Criteria for Registration Under the Standard	II-3
	F. Acceptable Ranges and Limits for Manufacturing-Use Terbacil	II-4
	Product Composition	II-4
	Acute Toxicity Limits	II-4
	Use Patterns	II-4
	G. Required Labeling	II-4
	Use Pattern Statements	II-4
	Precautionary Statements	II-4
	H. Tolerance Reassessment	II-4
III.	Data Requirements and Data Gaps	III-1
	Tables A - Generic Data Requirements for Terbacil Manufacturing-use Products	III-1
	Product Chemistry	III-2
	Environmental Fate	III-6
	Toxicology	III-10
	Residue Chemistry	III-14
	Ecological Effects	III-22
IV.	Product Chemistry	
	A. Chemistry Profile	IV-1
	B. Manufacturing-Use Terbacil	IV-1
	Chemical Identity	IV-1
	Manufacturing Process	IV-2
	Formation of Unintentional Ingredients	IV-2
	Percent of Active Ingredient in Pesticide Products	IV-2
	Product Analytical Methods and Data	IV-2
	Physical and Chemical Properties	IV-3
	C. Required Labeling	IV-3
	D. Data Gaps	IV-3
V.	Environmental Fate	
	A. Use Summary	V-1
	B. Environmental Fate Profile	V-1
	C. Manufacturing-Use Terbacil	V-5
	D. Exposure Profile	V-13
	E. Data Gaps	V-14

VI. Toxicology
A. Toxicology Profile VI-1
B. Manufacturing-Use Terbacil VI-2
C. Data Gaps VI-6

VII Residue Chemistry
A. Residue Chemistry Profile VII-1
B. Metabolism in Plants VII-1
C. Metabolism in Animals VII-2
D. Analytical Methods VII-2
E. Residue Data VII-3
F. Data Gaps VII-12

VIII. Ecological Effects
A. Ecological Effects Profile VIII-1
B. Manufacturing-Use Terbacil VIII-1
C. Hazard Assessment VIII-3
D. Data Gaps VIII-4

IX. Bibliography IX-1
Guide to use of Bibliography
Case Bibliography

CHAPTER I: HOW TO REGISTER UNDER A REGISTRATION STANDARD

A. Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second chapter involves the regulatory position and the rationale supporting this position. The third chapter sets forth the data requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapter, the Agency reviews the available data by scientific descipline, and discusses the Agency's concerns with the identified potential hazards.

B. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursant to Section 3(c)(5) that:

(A) its compostition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended fuction without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. However, the established approach to making these findings has been found to be defective on two counts.

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many

pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the

data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978) many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as were being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision, of an applicator who has been certified by the State of Federal government as being competent to use the pesticide safely, responsibly, and in acccordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

The Standard will directly register or reregister only manufacturing use products and their intermediries. End-use products will be registered or reregistered under a separate Label Improvement Program. The only exception to this general rule will arise when there is no manufacturing-use product registered for a particular end-use product. In this case, the end-use product will be treated as if it were a manufacturing-use product.

The Agency has separated the reregistration of end-use products from that of manufacturing-use products in order to increase the rapidity with which products may be reregistered and to place emphasis on the concern for chronic health effects data which prompted the legislative requirement for reregistration. The utility of this approach is the product of two factors. First, end-use product specific data requirements are minimal and can be more effectively handled through a separate process. Second, a separate process obviates many of the difficulties inherent in reregistration of products which are mixtures of more than one active ingredient and will ultimately be affected by several Standards. Under the Label Improvement Program, end-use products will be reregistered on a separate schedule from the reregistration of manufacturing-use products.

The Standard will consider all uses of the active ingredient which are registered for end-use products at the time the Standard is developed, including use patterns which pertain only to mixtures. The Standard will also establish labeling requirements for manufacturing-use products which formulators of end-use products will have to follow. However, the imposition of these labeling requirements directly on formulators will fall under the Label Improvement Program.

C. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with the Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

D. "Product-Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects.

These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are need to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1. Data that are product specific, i.e., data that relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar compostion); and

2. Generic data that pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product-specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any manufacturing-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product-sepcific" data on any product other than the applicant's are irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.)

All other data needed to evaluate pesticide products concern the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient (e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed guidelines, 43 FR 37355).

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed

40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide.

If a registrant of a currently registered manufacturing-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that are required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

E. Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered are all data which are described by all of the following criteria:

1. The data were first submitted to EPA (or to its predecessor agencies, USDA or FDA) on or after January 1, 1970.

2. The data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain an existing registration.

3. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s).

4. The Agency has found the data to be valid and usable in reaching regulatory conclusions.

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in

determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product-specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(c)(1)(D) for those data.

Each applicant for registration or reregistration of a manufacturing-use product must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to that product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

F. Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects or products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps."

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, the product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that, to be registrable under the Standard, a product must be supported by certain required "product-specific" data.

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps - whether the data in question are "product-specific" or "generic" - in accordance with a schedule.

Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

G. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date to prior the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any

subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

Chapter II
Agency Position on Terbacil

A. Introduction

This chapter describes in detail the Agency's regulatory position on manufacturing-use products which contain terbacil as the sole active ingredient, and reflects a review only of terbacil in manufacturing-use products and not of other active ingredients in a mixture. The regulatory position adopted by the Agency incorporates a number of considerations. Foremost among these considerations is an analysis of the registrability of manufacturing-use products containing terbacil based on the risk criteria found in Section 162.11(a) of Title 40 of the U. S. Code of Federal Regulations. The Agency's determination is presented below, and the rationale for this decision follows the position.

In addition to the basic regulatory decision and retaionale, this chapter includes the following: criteria for the registration of terbacil manfacturing-use products under the Standard; acceptable ranges and limits for product composition, acute toxicity, and use pattern/application method; required labeling; tolerance assessment.

The scientific basis for the decision presented in this chapter can be found by reading the various disciplinary summaries which are found in Chapters IV-VIII of this Standard. References to Agency guidelines for testing are provided when appropriate. In instances where the data requirements differ from the guideline requirements, the rationale is presented in the footnotes of the table.

B. Description of Chemical

Terbacil is the common name for 5-chloro-3[1,1-dimethyl]-6-methyl-2,4[1H,3H]-pyrimidinedione, a substitute uracil herbicide that is effective in controlling certain perennial grasses and annual weeds. The registered use sites include apples, peaches, alfalfa, mint (peppermint, spearmint), sugarcane, strawberries, pecans, blueberries, caneberries (blackberries, boysenberries, dewberries, loganberries, raspberries, youngberries), and citrus.

The basic producer of terbacil is E. I. du Pont de Nemours Company, Incorporated. Technical terbacil is classified as a manufacturing-use product intended to be used only for reformulation into end-use pesticides. Terbacil is formulated as an 80% active ingredient wettable powder. Terbacil is also formulated with diuron under the trade name Zobar. However, discussions of formulations and those containing more than one active ingredient are not included in this Standard.

Terbacil is a crystalline solid which contains a minumum of 95% active ingredient. This chemical is non-volatile and stable when stored under normal conditions. It is slightly soluble in water and partially to very soluble in organic solvents. The mechanism of action for terbacil is the inhibition of photosynthesis. Terbacil has a residual phytotoxicity in soil of from one to two years at normal application rates.

Terbacil is the approved ANSI name in the United States. It is also known under the trade name Sinbar. Other chemical names include 5-chloro-3-[1,1-dimethyl]-6-methyl-2,4[1H,3H](9CI) and 3-tert-butyl-5-chloro-6-methyluracil (8CI). The molecular weight of terbacil is 216.7 and the empirical formula for terbacil is $C_9 H_{13} ClN_2O_2$. The patent number is 3,352,862; the chemical asbtracts registry (CAS) number is 5902-51-1. The EPA Shaughnessy Number is 012701.

C. Regulatory Position for Manufacturing-use Products Containing Terbacil

Terbacil, 5-chloro-3-[1,1-dimethyl]-6-methyl-2,4[1H,3H]-pyrimidinedione, as described in this Standard may be registered for sale, distribution, reformulation, and use in the United States. Considering all information available to the Agency from the open literature and provided to the Agency by the registrant as of March 1982, the Agency finds that none of the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations were met or exceeded for pesticide products containing terbacil.

A review of the data base indicates that the use of terbacil will not result in unreasonable adverse effects to man or the environment. Currently, registered terbacil products may be reregistered subject to the conditions imposed. New manufacturing-use products and new uses may be registered under this Standard and are subject to the same requirements.

D. Regulatory Rationale

Terbacil is a selective herbicide registered to control certain perennial grasses and annual weeds. The major domestic use of terbacil is application to sugarcane in Louisiana and Texas, with smaller volumes being applied to apples and alfafa in the U.S., and to peaches in the eastern regions of the United States. Sugarcane accounts for 75% of the annual terbacil usage, whereas apples, alfalfa, and peaches account for 14%, 5%, and 6%, respectively, of the annual usage.

Data gaps exist in the product chemistry data base. Data on the manufacturing process and the analytical methods used for the identification and quantification of terbacil in the technical material have been submitted by the registrant. Most of the physical and chemical properties for the technical material have been reported.

The environmental fate data base is incomplete. The available data are insufficient to fully assess the fate of terbacil in the environment. A special estuarine monitoring study will be needed to determine the necessity to conduct chronic toxicity studies on shrimp and estuarine fish. This study is needed to determine the potential exposure of non-target organisms, including wildlife associated with the potential contamination of surface waters in proximity of sugarcane fields treated with terbacil.

The toxicology data base is incomplete. Available acute toxicity data indicate a low toxicity potential to humans. There are no chronic or oncogenic hazards associated with terbacil as indicated by the experimental data. One oral teratology study demonstrates findings of hydrophnephrosis in

the test animals in the dosed groups. Hydrophnephrosis is the dilation of the renal pelvis and ureter. Based on the avaiable test data, these findings observed at significant levels in the test animals is considered a teratogenic response. The dilation of renal pelvis and/or hydroureter may be attributed to other factors such as development growth retardations reversible with growth (fetotixicity) or normal background incidence. If the registrant can demonstrate with adequate historical data that the hydronephrosis found in the dose groups in the oral teratology study is within normal limits, a repeated study will not be required.

Data gaps have been identified in the residue chemistry data base. Additional residue data may be required for the processed products of apples, citrus, peaches, pears, and pecan shells. The metabolism of terbacil on plants and animals is adequately documented. Adequate methods of determining residues of terbacil in various commodities exist. Residue studies reflecting the registered uses of terbacil on raw agricultural crops, by-products and feed items are acceptable. The established tolerances for residues of terbacil are found to be adequate based on the evaluation of the residue data.

Cover crops contain residues. To avoid the ingestion of residues from these crops, a general label restriction against the grazing or feeding of cover crops to livestock will be required in apple, pear and peach orchards and in citrus groves. Currently there is a restriction only against the grazing of livestock in treated pecan orchards.

The ecological effects data base is incomplete. Adequate data exist on the acute toxicity of terbacil to indicate that is not highly toxic to birds, fish, and aquatic invertebrates. Estuarine and marine organisms may be exposed to terbacil due to its use as a sugarcane herbicide.

E. Criteria for Registration Under the Standard

To be subject to this Standard, manufacturing-use terbacil products must meet the following conditions:

- contain terbacil as the sole active ingredient;
- be within acceptable standards of product composition;
- be within acute toxicity limits;
- be labeled for acceptable uses; and
- bear required labeling.

The applicant for registration or reregistrarion of terbacil manufacturing-use products subject to the Standard must comply with all terms and conditions decribed in this Standard, including commitment to fill data gaps on a time schedule specified by the Agency, and when applicable offer to pay compensation to the extent required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

F. Acceptable Ranges and Limits for Manufacturing-use Terbacil

1. Product Composition

To be covered under this Standard, manufacturing-use terbacil must contain terbacil as the sole active ingredient. Manufacturing-use terbacil products with any percentage of active ingredient with appropriate certification of limits are acceptable under this Standard.

2. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use terbacil products which have established acute toxicity I-IV ratings for each of the following effects:

	I	II	III	IV
Acute Oral Toxicity	yes	yes	yes	yes
Acute Dermal Toxicity	yes	yes	yes	yes
Acute Inhalation Toxicity	yes	yes	yes	yes
Primary Eye Irritation	yes	yes	yes	yes
Primary Dermal Irritation	yes	yes	yes	yes

3. Use Patterns

To be covered under this Standard, manfacturing-use terbacil products must be labeled to allow for formulation into end-use herbicides which are intended for outdoor domestic use application.

G. Required Labeling

All manufacturing-use terbacil products must bear appropriate labeling as specified in 40 CFR 162.10, as discussed elsewhere in this guidance package.

1. Use Pattern Statements

All manufacturing-use terbacil products must list on the label the intended end-uses of formulated products produced from the manufacturing-use product. In accordance with data submitted or cited, all terbacil labels must bear the following statement: "For Formulation into End-Use Herbicide Products Intended Only for Domestic Food (Non-Food) Terrestrial Outdoor Use."

2. Precautionary Statements

There are no unique precautionary statements which must appear on the terbacil label. The guidance package provides an updated list of all precautionary statements which must appear for this type of product. The Agency may, after review of data to be submitted under this Standard, impose additional label requirements.

H. Tolerance Reassessment

The following tolerances for terbacil and Metabolites A, B, And C have been established as stated in 40 CFR 180-209, as of July 1, 1981.

The earliest tolerances of 0.1 ppm were established for residues of terbacil alone in or on the following raw agricultural commodities: apples, citrus fruits, peaches, pears, sugarcane.

Later tolerances were established for combined residues of terbacil and Metabolites A, B, and C in or on the following raw agricultural commodities:

	Parts per million
Alfalfa, Forage	5.0
Alfalfa, hay	5.0
Asparagus	0.2
Blueberries	0.1
Caneberries (blackberries, boysenberries, dewberries, loganberries, raspberries, and youngberries)	0.1
Cattle, fat	0.1
Cattle, mbyp	0.1
Cattle, meat	0.1
Goats, fat	0.1
Goats, mbyp	0.1
Goats, meat	0.1
Hogs, fat	0.1
Hogs, mbyp	0.1
Hogs, meat	0.1
Milk, fat (=0.1 in whole milk)	0.5
Mint hay (peppermint, spearmint)	2.0
Pecans	0.1
Sainfoin, forage	5.0
Sainfoin, hay	5.0
Sheep, fat	0.1
Sheep, mbyp	0.1
Sheep, meat	0.1
Strawberries	0.1

In Canada, a tolerance of 0.1 ppm exists for residues of terbacil alone for the following commodities: alfalfa, apples, citrus, peaches, blueberries, and strawberries. No tolerances exist in Mexico, and no maxium residue limit has been established by the Codex Alimentarius Commission.

Residue crop group tolerances are in effect for citrus and caneberries. The crop group for non-grass animal feeds cannot be included due to the absence of residue data on the second representative crop, clover.

No record of regulatory activity involving the enforcement of terbacil tolerances by FDA was submitted.

The Acceptable Daily Intake (ADI) is 0.0125 mg/kg/day, the Maximum Permissible Daily Intake (MPI) is 0.75 mg/day (based on a 60 kg body weight). The Theoretical Maximum Residue Contribution (TMRC), based on the relevant food factors and tolerances for applies, citrus, peaches, pears sugar, blueberries, red meat, milk and dairy products, strawberries, mint, pecans, caneberries, and asparagus, is 0.0778 mg/day assuming a 1.5 kg diet. Therefore the established tolerances for residues of terbacil are adequate based on the evaluation of the residue data.

Chapter III

Data Requirements and Data Gaps

A. Manufacturing-use Terbacil

Table A, entitled Generic Data Requirements, includes those data that pertain to the properties or effects of terbacil as an active ingredient. Thus, these data are relevant to an evaluation of the risks and benefits of all manufacturing-use products containing terbacil. Providing data to fill indicated gaps is the primary responsibility of the manufacturing-use product registrants. Registrants of end-use products which are not exempted by FIFRA Section 3(c)(2)(D) are also responsible for the submission of these data. Applicants for the registration or reregistration of manufacturing-use terbacil products must acknowledge reliance on existing data which fill indicated data requirements under FIFRA 3(c)(1)(D). These data are listed under the column entitled Bibliographic Citation in this table.

Product-specific data requirements for manufacturing-use products include those data that relate only to the properties or effects of a product with a specific composition. Thus, these data are required of each product to characterize the product's particular composition and physical/chemical properties, and acute toxicity. Providing data to fulfill these data requirements for a particular product is the responsibility of each applicant for the registration or reregistration of a manufacturing-use terbacil product. If the Agency has in its possession product-specific data which fulfill a data requirement for a particular product, this is indicated in the guidance package accompanying this Standard.

Applicants for the registration of new manufacturing-use terbacil products must submit all required product specific data or establish that the proposed product is substantially similar to another product for which the Agency has received acceptable product specific data.

If the Agency has determined that one or more existing manufacturing-use terbacil products are substantially similar, then this, too, is indicated. Product specific data need not be acknowledged under FIFRA 3(c)(1)(D) unless the Agency or a registrant has established that a product is substantially similar to another product for which the Agency has received acceptable product specific data. If this should occur, the registrant of the former product is required to acknowledge reliance on these data.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Product Chemistry						
163.61-3	Product Identity and Disclosure of Ingredients	Yes	95% Technical Grade	Yes	Du Pont, 1973 MRID 00011958 Du Pont, 19?? MRID 00012364	No
163.61-4	Description of Manufacturing Process	Yes	95% Technical Grade	Partially[1]	Du Pont, 1974 MRID 00011954 Du Pont, 19?? MRID 00012366	Yes, 3 months
163.61-5	Discussion of Formaton of Unintentional Ingredients	Yes	95% Technical Grade	Yes	Du Pont, 19?? MRID 00012364	No
163.61-6	Declaration and Certification of Ingredient Limits	Yes	95% Technical Grade	Partially[2]	Du Pont, 19?? MRID 00012364	Yes, 1 year
163.61-7	Product Analytical Methods and Data	Yes	95% Technical Grade	Yes	Du Pont, 19?? MRID 00012365	No

1/ The yield of the reactions of the intermediate and final product are not given.
2/ Available data did not include certification limits.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Product Chemistry						
163.61-8(c)(1)	Color	Yes	95% Technical Grade	Yes	Du Pont, 1973 MRID 00011958	No
163.61-8(c)(2)	Odor	Yes	95% Technical Grade	Yes	Du Pont, 1973 MRID 00011958	No
163.61-8(c)(3)	Melting Point	Yes	95% Technical Grade	Yes	Du Pont, 1973 MRID 00011958	No
163.61-8(c)(4)	Solubility	Yes	95% Technical Grade	Yes	Du Pont, 1973 MRID 00011958	No
163.61-8(c)(5)	Solubility	Yes	95% Technical Grade	No		Yes, 3 months
163.61-8(c)(6)	Octanol/Water Partition Coefficient	Yes	95% Technical Grade	No		Yes, 3 months

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Product Chemistry						
163.61-8(c)(7)	Physical State	Yes	95% Technical Grade	Yes	Du Pont, 1973 MRID 00011958	No
163.61-8(c)(8)	Odor	Yes	95% Technical Grade	Yes	Du Pont, 1973 MRID 00011958	No
163.61-8(c)(9)	Melting Point	Yes	95% Technical Grade	Yes	Du Pont, 1973 MRID 00011958	No
163.61-8(c)(10)	Solubility	Yes	95% Technical Grade	Yes	Du Pont, 1973 MRID 00011958	No
163.61-8(c)(11)	Solubility	Yes	95% Technical Grade	No		Yes, 3 months
163.61-8(c)(12)	Octanol/Water Partition Coefficient	Yes	95% Technical Grade	No		Yes, 3 months

1/ Since terbacil has very low solubility in water, data are not required.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Product Chemistry						
163.61-8(c)(13)	Flammability	No				No[2]
163.61-8(c)(14)	Oxidizing or Reducing Action	Yes	95% Technical Grade	No		Yes, 3 months
163.61-8(c)(15)	Explosiveness	Yes				Yes, 3 months
163.61-8(c)(16)	Miscibility	No	95% Technical Grade	Yes		No
163.61-8(c)(17)	Viscosity	No				No[3]
163.61-8(c)(18)	Corrosiveness	Yes	95% Technical Grade	No		Yes, 12 months

2/ Data on flammability are not required because terbacil is a solid with a high melting point.
3/ Data on viscosity are not required since terbacil is a solid at room temperature.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Environmental Fate						
1. Degradation						
163.161-1	Hydrolysis	Yes	RLAG/TGAI*	Partially[1]	Rhodes, 1975 MRID 00011946	Yes, 2 years
163.161-2c(2)	Photodegradation in water	Yes	RLAG/TGAI	Yes	Rhodes, 1975 MRID 00011946 Acher, 1981 MRID 00390011	No
163.161-3	Photodegradation on soil	Yes	RLAG/TGAI	No		Yes, 2 years
163.161-4	Photodegradation in Air	Yes				No
2. Metabolism						
163.162-1	Aerobic soil	Yes	RLAG/TGAI	No		Yes, 2 years
163.162-2	Anaerobic soil	Yes	RLAG/TGAI	No		Yes, 2 years
163.162-3	Anaerobic aquatic	No				No
163.162-4	Aerobic aquatic	No				No

*/ Radiolabeled Analytical Grade/Technical Grade of Active Ingredient.

1/ An additional study at 25°C is needed to fully assess the hydrolysis of terbacil.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Environmental Fate						
3. Microbial						
-	Metabolism	Reserved[2]				
-	Effects of Microbes on Pesticides	Reserved[2]				
-	Effects of Microbes on Pesticides	Reserved[2]				
-	Activated sludge metabolism	Reserved[2]				
4. Mobility						
163.163-1	Leaching	Yes	RLAG/TGAI*	Partially	Davidson, 1978 MRID 05014424 Liu, 1971 MRID 05014175 Rao, 1979 MRID 05008371	Yes[3] 2 years
163.163-2	Laboratory Volatility	No				No
163.163-3	Field Volatility	No				No

2/ The requirement for the submission of these data is currently being reserved pending the development and modification of the testing protocols.

3/ Available studies partially fulfill data requirements for mobility by providing data on the adsorption of terbacil to soils ranging in texture from sand to clay. Soil thin layer chromatography, soil column, or batch equilibrium (desorption) data are needed to fully assess the mobility of terbacil in soil.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required		Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Environmental Fate							
5. Dissipaton							
163.164-1	Field Dissipation: Terrestrial	Yes	RFP*	No		Yes, 24 months	
163.164-2	Field Dissipation: Aquatic & Aquatic Impact	No		No		No	
163.164-3	Dissipation: Forestry	No		No		No	
163.164-4	Dissipation: Combination and Tank Mixes	No		No		No[4]	
163.164-5	Dissipation: Long Term Studies	Yes	RFP*	No		Yes, 24 months	

* Representative formulated product.

4/ Not applicable to a single active ingredient standard.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Environmental Fate						
6. Accumulation						
163.165-1	Confined Accumulation-Rotational Crops	Yes	RLAG/TGAI*	Yes	Du Pont, 1975 MRID 00011948 Holt, 1971 MRID 00011949	No
163.165-2	Field Accumulation Rotational Crops	Yes				No[5]
163.165-3	Accumulation - Irrigated Crops	No				No
163.165-4	Laboratory Studies Fish	Yes	RLAG/TGAI*	Yes	Rhodes, 1969 MRID 00011947	No
163.165-5	Field Accumulation Aquatic Non-target	No				No
7. Subpart K	Reentry	No				No
8. Special Study	Monitoring	Yes	RFP**	No		Yes, 24 months[6]

* Radio-labeled Analytical Grade/Technical Grade of Active Ingredient. ** Representative Formulated Product

5/ The use patterns indicate that terbacil is used on crops which are not grown in rotation with other crops.

6/ An estuarine monitoring study on a selected estuary adjacent to sugarcane fields will be used to determine necessity to conduct chronic toxicity studies on shrimp and estuarine fish. Refer to Table A, footnote 3, pages 3-22. A protocol must be submitted before initiating the study.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Core Data	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Toxicology							
163.81-1	Acute Oral Toxicity	Yes	Technical Grade	No			Yes: 12 months
163.81-2	Acute Dermal Toxicity	Yes	Technical Grade	No			Yes: 12 months
163.81-3	Acute Inhalation	Yes	Technical Grade	No			Yes: 12 months[2]
163.81-4	Primary Eye Irritation	Yes	Technical Grade	Partially	Du Pont, 1964 MRID 0039006	Supplementary	Yes: 12 months[2]
163.81-5	Primary Dermal Irritation	Yes	Technical Grade	Partially	Du Pont, 1965 MRID 0039007	Supplementary	Yes: 12 months[3]
163.81-6	Dermal Sensitization	Yes	Technical Grade	Partially	Du Pont, 1965 MRID 0039007	Supplementary	Yes: 18 months[4]
163.81-7	Acute Neurotoxicity	No	Technical Grade	No			No

1/ Submit the required inhalation studies or data on particular size.

2/ A complete standard primary eye irritation study should be conducted because the available study had an insufficient observation period, used too few animals and eyes were not scored. If this study is determined to be valid, additional testing will not be needed.

3/ This report provides summary data. A complete standard primary dermal irritation study should be conducted.

4/ The test animals (guinea pigs) were not sensitized in this study. But because positive controls were not provided, the study should be repeated.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Core Data	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Toxicology							
163.82-1	Subchronic Oral Toxicity	Yes	Technical Grade	Yes	Du Pont, 1964	Minimum MRID 00300009	No
163.82-2	Subchronic 21-day dermal Toxicity	Yes	Technical Grade	Yes	Du Pont, 1966	Supplementary MRID 00012235	Yes, 12 months[5]
163.82-3	Subchronic 90-day dermal Toxicity	No					No
163.82-4	Subchronic Inhalation Toxicity	No					No

5/ Insufficient dose levels were used and a complete study was not available. This study should be repeated using the proper testing guidelines stated in Section 163.82-2.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Core Data	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Toxicology							
163.83-1	Chronic Feeding	Yes	80%	Yes	International Research and Development Corporation, 1967 MRIDs 00390001, 0039002	Minimum	No
163.83-2	Oncogenicity	Yes	80% WP	Yes	International Research and Development Corporation, 1967 MRIDs 0039002	Minimum	Yes, 48 months
163.83-3	Teratogenicity	Yes	Technical Grade	Yes	Du Pont, 1980 MRID 00390010	Supplementary	Yes, 36 months[6]
163.83-4	Reproduction	Yes	80% WP	Yes	International Research and Development Corporation, 1967 MRIDs 0039003	Supplementary	Yes, 36 months[6]

6/ To determine whether the dilations of the renal pelvis and ureter that was found in the test groups are a true teratogenic response or whether they are a result of fetotoxicity, an additional rat post-natal evaluation must be conducted.

7/ Due to audit deficiencies and study design, this test must be repeated.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Core Data	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Toxicology							
162.84-2 through 4	Mutagenicity	Yes	Technical Grade	Partially	Anderson, 1972 MRID 05016657 Murnik, 1976 MRID 05017208 McGahen, 1965 MRID 00013309		Yes, 48 months[8]
162.84-2	Mutagenicity	Yes	2-^{14}C-terbacil	Yes	Anderson, 1973? MRID 00011950 Rhodes, 1974? MRID 00011957 Du Pont, 19?? MRID 00011954 Gardiner, 19?? MRID 00012030	Supplementary	Yes, 36 months[9]

8/ In addition to a complete study on gene mutation, registrants will be required to provide data from studies to detect primary DNA damage and chromosomal aberrations.

9/ Metabolism studies in the laboratory rat were not conducted. A standard metabolism study, preferably in the laboratory rat, should be conducted in accordance with the Guideline Section 163.85-1.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Residue Chemistry						
—	Metabolism in plants	Yes	Residues of active ingredient and its metabolites of toxicological concern	Yes	Rhodes, 1964, MRID 00011965 Rhodes, 1977 MRID 05013216 Rhodes, 19?? MRID 00012014 Gardiner, 1969 MRID 05002415 Jordan, 1975 MRID 05013598	Yes[1]
—	Metabolism in animals	Yes	As above	Yes	Pease, 1964 MRID 00011950 Gutenmann, 1969 MRID 05002373	No
—	Analytical methods	Yes	As above	Yes	Pease, 1964 MRID 00012035 Pease, 1968 MRID 05012979 Pease/Leitch/Hunt, 1978 MRID 05014422 Holt/Pease, 1977 MRID 05015405 Holt/Pease, 1977 MRID 00011949	No

1/ The need for additional data is conditional on a change in the expression of the tolerance from terbacil alone to terbacil and metabolites A, B, and C.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Residue Chemistry						
—	Analytical methods (con't)	Yes	Residues of active ingredient and its metabolites of toxicological concern	Yes	Cessna, 1977 MRID 05015405 Holt/Pease, 1971? MRID 00011960 Du Pont, 19?? MRID 00011961 Pease, 19?? MRID 00012181 Pease 19?? MRID 00011953 Pease, 1971? MRID 1235 Du Pont, 19?? MRID 1237	No
—	Residue data: Crops					
—	Alfalfa forage	Yes	As above	Yes	Du Pont, 1973, MRID 00011959 Rhodes, 1964 MRID 00011965 Rhodes, 1977 MRID 05013216	No

1/ The need for additional data is conditional on a change in the expression of the tolerance from terbacil alone to terbacil and metabolites A, B, and C.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Residue Chemistry						
—	Residue data: crops					No
—	Alfalfa hay	Yes	Residues of active ingredient and its metabolites of toxicological concern	Yes	Du Pont, 1973 MRID 00011959 Rhodes, 1964 MRID 000111965 Rhodes, 1977 MRID 05013216	No
—	Apples	Yes	As above	Yes	Stauffer, 1980 MRID 00070784 Du Pont, 1973 MRID 00012402 Du Pont, 1966 MRID 00012015	Yes[1]
—	Asparagus	Yes	As above	Yes	International Research and Develop., 1976 MRID 00028524	No
—	Blueberries	Yes	As above	Yes	Rutgers, 1973 MRID 00012039	No

1/ The need for additional data is conditional on a change in the expression of the tolerance from terbacil alone to terbacil and metabolites A, B, and C.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Residue Chemistry						
—	Residue data: crops					No
—	Caneberries	Yes	Residues of active ingredient and its metabolites of toxicological concern	Yes	Holt/Pease, 197? MRID 00390015	No
—	Citrus fruit	Yes	As above	Yes	California Citrus Res. Center, 1966 MRID 00012232 Du Pont, 1966 MRID 00012015	Yes[1]
—	Mint hay	Yes	As above	Yes	Du Pont, 1975 MRID 00012067	No
—	Peaches	Yes	As above	Yes	Du Pont, 1973 MRID 00012067	Yes[1]
—	Pears	Yes	As above	Yes	Du Pont, 1973 MRID 00012015	Yes[1]

1/ The need for additional data is conditional on a change in the expression of the tolerance from terbacil alone to terbacil and metabolites A, B, and C.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Residue Chemistry						
—	Residue data: crops					
—	Pecans	Yes	Residues of active ingredient and its metabolites of toxicological concern	Yes	Du Pont, 1977 MRID 00390016	No
—	Sainfoin forage	Yes	As above	Yes	Du Pont, 1973 MRID 00011959 Rhodes, 1974 MRID 00011965 Rhodes, 1977 MRID 05013216	No
—	Sainfoin hay	Yes	As above	Yes	Du Pont, 1973 MRID 00011959 Rhodes, 1964 MRID 00011965 Rhodes, 1977 MRID 05013216	No

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Residue Chemistry						
—	Residue data: crops					
—	Strawberries	Yes	Residues of active ingredient and its metabolites of toxicological concern	Yes	Rutgers, 1972 MRID 00012097	No
—	Sugarcane	Yes	As above	Yes	Du Pont, 1966 MRID 00012179 Du Pont, 1966 MRID 00012180	Yes[1]
—	Residue data: processed commodities	Yes	As above	Yes	Du Pont, 1975 MRID 00012067 Du Pont, 1966 MRIDs 00012103, 00012179, 00012180 000390023	Yes[2]

1/ The need for additional data is conditional on a change in the expression of the tolerance from terbacil alone to terbacil and metabolites A, B, and C.

2/ Residue data on processed products are only available for sugarcane bagasse and molasses and mint oil (see Topical Discussion for details). Additional data may be required for processed products of apples, citrus, peaches, pears, and pecan shells.

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Residue Chemistry						
—	Residue data: meat, milk, poultry, and eggs	Yes	Residues of active ingredient and its metabolites of toxicological concern	Yes	Du Pont, 19?? MRID 00011945 Du Pont, 19?? MRID 00011963 Du Pont, 1974 MRID 00011957	No
—	Storage	Yes	As above	Yes	—	No

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Residue Chemistry						
163.71-1	Avian Single-Dose Oral LD_{50}	Yes	Technical Grade	No		Yes, 12 months
163.71-2	Avian Dietry or LC_{50}	Yes	Technical Grade	Yes	Wazeter, 1966 MRID 00012347 Moore, 1979 MRID 00390020 Wazeter, 1966 MRID 00012346	No
163.71-3	Mammalian Acute Toxicity	No				No
163.71-4	Avian Reproduction	No				No
163.71-5	Simulated and Actual Field Testing for Mammals and Birds	No				No

TABLE A

Data Requirements for Terbacil Manufacturing-use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard
Ecological Effects						
163.72-1	Fish Acute LC_{50}	Yes	Technical Grade	Yes	Smith, 1980 MRID 00390017 Summers, 1978 MRID 00390019	No
163.72-2	Aquatic Toxicity to Aquatic Invertebrates	Yes	Technical Grade	Yes	McCann, 1981 00390018	No
163.72-3	Aquatic Toxicity to Estaurine and Marine Organisms	Yes	Technical Grade	Partially[1]	Bentley, 1973 MRID 00012332	Yes, 12 months[2]
613.72-4	Embryolarvae and Life-cycle Studies of Fish and Aquatic Invertebrates	Reserved	Technical Grade	No		No[3]
163.72-5	Life-cycle of Fish	Reserved	Technical Grade	No		No[3]
163.72-6	Aquatic Organism Toxicity and Residue Studies	No				No
163.72-7	Simulated or Actual Field Testing for Aquatic Organisms	No			No	

1/ The requirement for a 96-hour LC_{50} on shrimp has been satisfied. An LC_{50} performed on a marine or estuarine fish and an oyster acute test (embryolarvae or shell deposition) must be submitted.

2/ Terbacil may be expected to enter the estuarine or marine environment due to its extensive use as a sugarcane herbicide.

3/ A life-cycle test performed on the marine mysid shrimp and a sheepshead minnow study may be requested pending additional environmental fate data.

Chapter IV

Product Chemistry

A. Chemistry Profile

Terbacil is the common name for 5-chloro-3-[1,1-dimethyl]-6-methyl-2,4[1H,3H]pyrimidinedione, a substituted uracil herbicide registered for the control of perennial grasses and annual weeds in sugarcane, apples, alfalfa, peaches, pecans, ornamentals, berries, citrus, and mint.

Terbacil is a crystalline solid which contains a minimum of 95% active ingredient. This chemical is non-volatile and stable when stored under normal conditions. It is slightly soluble in water and partially to very soluble in organic solvents.

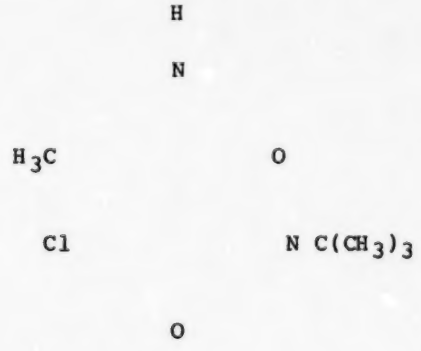
Technical terbacil is classified as a manufacturing-use product intended to be used only for reformulation into end-use products. Terbacil is formulated as an 80% active ingredient wettable powder. Terbacil is also formulated with diuron under the trade name Zoehar®. However, discussions of formulations and those containing more than one active ingredient are not included in this Standard.

B. Product Chemistry - Manufacturing-Use Terbacil

1. Chemical Identity

Terbacil is the approved ANSI common name for the chemical 5-chloro-3-[1,1-dimethyl]-6-methyl-2,4[1H,3H]pyrimidinedione (9CI) in the United States. Other chemical names include and 3-tert-butyl-5-chloro-6-methyluracil (8CI). The trade name of the formulated terbacil product is Sinbar®.

The empirical formula for terbacil is $C_9H_{13}ClN_2O_2$ and its molecular weight is 216.7. The structural formula is



E.I. du Pont de Nemours and Company, Wilmington, Delaware, is the basic producer of terbacil. The U.S. Patent Number is 3,352,862. The CAS Registry Number is 5902-51-1. The EPA Shaughnessy Number is 012701.

2. Manufacturing Process

Available data found in Appendix A (DuPont, MRID 00011954) and Appendix B (DuPont, MRID 00012366) to this Standard contain confidential information on the manufacturing process and purity of the starting materials, solvents and reagents used in the manufacturing of technical terbacil. A discussion on this information is not included in this Standard.

3. Formation of Unintentional Ingredients

Data have been submitted by DuPont (MRID 00012364) on the impurities present in technical terbacil and can be found in Appendix C to this Standard.

4. Percent of Active Ingredients in Pesticide Products

A confidential statement of formulation submitted by DuPont shows that technical terbacil contains a minimum of 95% terbacil as the active ingredient (MRID 00012364). The remaining components are manufacturing impurities which are detailed in Appendix C.

5. Product Analytical Methods and Data

Several analytical methods are available for terbacil. Pease et al. (MRID 05014422) describes two analytical methods to quantify technical and formulated terbacil. One is a liquid chromatographic (LC) method which uses a UV detector and an internal standard. An alternate method involves the use of infrared spectrophotometry to determine technical and formulated terbacil.

An analytical method has been submitted by DuPont to determine and quantify one of the impurities in technical terbacil (MRID 00012365). This method uses reverse-phase high performance liquid chromatography and UV detector and digital integrator in technical and formulated terbacil products.

This method simultaneously measures terbacil and one of the impurities present in technical terbacil and thus meets the requirement for identification and quantification of the active ingredient and impurities in technical and formulated terbacil.

Methods are available to measure terbacil with or without the one impurity and meet the requirement for identification and quantification of the active ingredient (with or without one impurity) in technical and formulated products.

A description of the methods used to identify and quantify other impurities present in technical terbacil is needed.

6. Physical/Chemical Properties

Technical terbacil and the manufacturing-use product are the same. Available information obtained from the Agency's files on the physical and chemical properties of technical terbacil and manufacturing-use terbacil are:

Color: White ----- (MRID 00011958)
Odor : None ------ (MRID 00011958)
Melting Point: 175-177°C ---------- (MRID 00011958)
Solubility: 25°C at 710 ppm in water ---- (MRID 00011958)

Solvents	(1 g terbacil in 100 g solvent)
dimethylformamide	33.7
cyclohexanone	22
methyl isobutyl ketone	13.8
butyl acetate	9.7
xylene	6.5

Physical state: crystalline solid ----------(MRID 00011958)
Specific gravity: 1.34 ----------(MRID 00011958)
Vapor pressure: 4.7×10^{-7} mmHg at 29.5°C (MRID 00011958)
5.4×10^{-6} mmHg at 54°C

C. Required Labeling

The ingredient statement for the manufacturing-use terbacil product will list the active ingredient as 5-chloro-3-[1,1-dimethyl]-6-methyl-2,4[H,3H]-pyrimidinedione _____%.

D. Data Gaps

1. The product chemistry data gaps for manufacturing-use terbacil are:

description of manufacturing process
declaration and certification of ingredient limits
analytical method and data (remaining impurities)

2. The physical/chemical data gaps for technical terbacil and manufacturing-use terbacil are

stability
octanol/water partition coefficient
storage stability
oxidizing or reducing action
explosiveness
corrosiveness

Chapter V

Environmental Fate

A. Environmental Fate Use Summary

Terbacil is a selective herbicide that is effective in controlling certain perennial grasses and many annual weeds. The registered use sites are apples, peaches, alfalfa, mint (peppermint, spearmint), sugarcane, strawberries, pecans, blueberries, caneberries, (blackberries, boysenberries, dewberries, loganberries, raspberries, youngberries), and citrus. The annual usage of terbacil is estimated, by the Agency's approximation, to range from 500,000 to 700,000 pounds active ingredient annually. The major domestic use of terbacil is for weed control on sugarcane in Louisiana and Texas with smaller volumes being applied to apples, alfalfa, peaches and pecans. Available data do not indicate exports or imports of terbacil.

B. Environmental Fate Profile

Available data are insufficient to fully assess the environmental fate of terbacil.

[^{14}C]Terbacil at 5 ppm was stable (<2% was degraded) in buffered aqueous solutions at pH 5, 7, and 9 for six weeks at 15°C in the dark (Rhodes, MRID 00011946). [^{14}C]Terbacil had a photolytic half-life of approximately 1 month in aqueous solution (Rhodes, MRID 00011946). After four weeks of irradiation with UV light (300-400 nm) 16% of the applied [^{14}C]terbacil (5 ppm) was photodegraded in distilled water (pH 6.2), 50% in standard reference water (pH 8.1, equivalent of an average or typical surface water in the U.S., (Freeman. 1953. Sewage Ind. Wastes 25:845), 27% in river water (pH 6.5), and >99% in standard reference water containing the photosensitizer riboflavin. The photodegradation products were 5-chloro-6-methyluracil, 3-tert-butyl-6-methyluracil, 3-tert-butyl-5-chloro-6-hydroxymethyluracil, 6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo(3,2-a)-pyrimidine-5-one, and two polar compounds. In standard reference water and river water, approximately 50-60% of the applied [^{14}C]-terbacil (5 ppm) was degraded in the standard reference water containing riboflavin. The photodegradation products were 5-chloro-6-methyluracil, 3-tert-butyl-6-methyluracil, and an unidentified compound. Under sunlight, terbacil (chromatographically pure) at 700 ppm was photodegraded in aqueous solutions containing methylene blue or riboflavin as a photosensitizer (Acher et al., MRID 00390011). The half-life of terbacil with either sensitizer at 35-38°C and at pH 7.8 was <2 hours. No degradation occurred under acidic conditions (pH 3.0-6.8) using methylene blue as the sensitizer. The degradation rate of terbacil with and without sensitizer decreased with decreasing pH and temperature. The major photodegration product was 3-tert-butyl-5-acetyl-5-hydroxyhydantoin. This compound was deacylated by nonphotochemical processes at > 15°C and pH ≥7.8 to yield 3-tert-butyl-5- hydroxyhydantoin. In acidic solutions (pH 3-6.8) with riboflavin as a sensitizer, a mono-N-dealkylated dimer and an unidentified oligomer were formed.

Data from soil metabolism studies indicated that terbacil (80% wettable

powder) at 100 ppm was slowly degraded in an aerobic sandy loam soil with 80% of applied remaining after 32 weeks at 23°C (Marsh and Davies, MRID 05013201). Terbacil at 8 ppm had a half-life of about 5 months in aerobic loam soil at 31°C (Zimdahl et al., MRID 005012290). [^{14}C]Terbacil at 2 ppm had a half-life of about 2-3 months in aerobic silt loam and sandy loam soils (Rhodes, MRID 00011946; Gardiner, MRID 00012208 and 005002414). The major identified degradation product was CO_2. Approximately 28% of the [^{14}C]terbacil applied at 2.88 ppm to an aerobic sandy loam soil was degraded to CO_2 in 600 days (Wolf and Martin, MRID 05016176; Wolf, MRID 05024336, 05013204). The addition of organic amendments to the soil increased the rate of degradation. Only trace amounts of [^{14}C]terbacil, applied at 2.88 ppm, were degraded to $^{14}CO_2$ after 145 days in anaerobic sandy loam soil. The addition of organic amendments to the anaerobic soil had no effect on the rate of terbacil degradation as determined by $^{14}CO_2$ evolution. In anaerobic silt loam and sandy soils, [^{14}C]terbacil at 2.1 ppm was slightly degraded (<5%) after 60 days at 20°C in the dark (Rhodes, MRID 00011946). [^{14}C]Terbacil at 2 ppm was slowly metabolized by microbes in the dark (Rhodes, MRID 00011946). At least 90% of the applied ^{14}C remained as terbacil after 90% days of incubation in both sterile and nonsterile soils. Small amounts (0.8-1.5% of applied ^{14}C) of CO_2 were evolved from nonsterile soil, whereas 0.01% was evolved from sterile soil. Three saprophytic soil fungi (Stachybotrus chartarum, Hendersonula toruloidea, and Epicoccum nigrum) were unable to produce $^{14}CO_2$ from [2-^{14}C]terbacil at 2.88 ppm during an 8-week incubation period (Wolf, MRIDs 05024336, 04013204). Terbacil ("pure compound"; 220-630 ppm) inhibited soil nitrification and the growth of nitrifying bacteria (Nitrosomonas and Nitrobacter) in soil and in culture (Ratnayake and Audus, MRID 05013602).

Terbacil, at 220-630 ppm in soil solutions, inhibited nitrate and nitrite formation by 50%. Terbacil (80% wettable powder) at 100 ppm had little or no effect on the O_2 uptake by microorganisms in two sandy loam soils but slightly stimulated nitrogen mineralization and CO_2 evolution (Marsh and Davies, MRID 05013201). Oxygen consumption in clay and sandy loam soils were not affected by terbacil (technical grade) at $\leq$250 ppm (Liu and Cibes-viade, MRID 05015406).

Growth of a Pseudomonas sp. and its parasite, Bdellovibrio bacteriovorus, was not inhibited by terbacil (wettable powder) at 2 mg/disk (Wehr and Klein, MRID 05015407). Paper discs treated with terbacil at 20 ug/disc did not inhibit the growth of Chlorella pyrenoidosa or Bacillus subtilis (Thomas et al., MRID 05018549).

Terbacil was mobile in soil. [^{14}C]Terbacil, applied at the equivalent of 2 lb ai/A, was mobile in 18-inch columns of a sandy loam soil but was comparatively less mobile in a silt loam soil (Rhodes, MRID 00011946). Approximately 64 and 0.4% of the applied radioactivity was eluted from unaged sandy loam and silt loam soil columns, respectively, leached with 20 inches of water. About 52 and 4% of the applied radioactivity aged in sandy loam and silt loam soils leached from the respective columsn in a degradate leaching study. Only 3-6 and 6.7.5 inches of water were necessary to elute detectable amounts of radioactivity from the aged and unaged soil columns, respectively.

However, the distribution of radioactivity in the columns was not determined. Terbacil was mobile in a fine sandy soil (Mansell et at., MRID 05017061). After application of [^{14}C]terbacil at 1 ppm followed by an equivalent of 15.5-20 acre-inches of a 0.01 M $CaSO_4$ solution, 73 and $\geq$90% of the applied radioactivity eluted from the 30 cm columns filled with soil collected at the 0-10 and 33-76 cm depths, respectively. Terbacil phytotoxic residues were mobile to depths of 27.5-30 cm in a sandy soil column treated with terbacil (80% wettable powder) at the equivalent of 5.6 kg/ha and eluted with 10 or 20 cm of water (Marriage et al., MRID 05013202). Terbacil was negligibly adsorbed to soils ranging in texture from sand to clay (Davidson et al., MRID 05014424; Rao and Davidson, MRID 05008371; Liu et al., MRID 05014175). Terbacil was adsorbed (54%) to a muck soil (36% organic matter) (Liu et al, 05014175).

Data from field dissipation studies showed that terbacil persistence in soil varied with application rate, soil type, and mobility. [^{14}C]Terbacil at 2 lb ai/A dissipated from the silt loam soil contained within 4 x 15-inch cylinders driven into the soil with a half-life of 1-2 months (Rhodes, MRID 00011946). ^{14}C residues were mobile to depths of 12-15 inches (maximum depth sampled) after receiving 18.3 inches of rainfall over a 4-month period. ^{14}C residues persisted for >1 year in a silt loam soil treated with [^{14}C]terbacil (>98% pure) at 4 lb/A (Gardiner et al., MRID 005002415); Gardiner, MRIDs 00012031, 00012032). The radioactive residues were mobile to 8-12 inches (maximum depth sampled) with 14% of the applied radioactivity persisting in the upper 12 inches of the treated soil 1 year after treatment. 5-Chlorouracil, a suspected degradation product, was not detected in the 0-1 and 8-12 inch soil segments of the 5- and 14-week samples. Terbacil at 4.5 kg/ha was mobile in a sandy soil (Mansell et al., MRIDs 05014421, 05017062). Terbacil was present at $\leq$100 ppb in subsurface drainage water samples (collected at a depth of 107 cm) after the plot received 18.4 cm of water. Between 0.5 and 1.8% of the applied terbacil leached to 107 cm. Therefore, a potential exists for residues of terbacil to contaminate ground water beneath sandy soils treated with terbacil, particularly when deep tillage cultural practices are used.

Thirteen months after application of terbacil at 2-16 lb/A to a clay soil, terbacil phytotoxic residues remained at 0.01-0.4 ppm in the upper 12 inches of soil (Liu et al., MRID 00017711). Terbacil, applied on a silty clay soil at 1.2 and 2.4 lb/A, persisted 7 months at levels that were extremely phytotoxic to cotton and slightly phytotoxic to sorghum (Isom et al., MRIDs 00028135, 05018594). These results were observed following an intervening crop and the application of 64 acre-inches of irrigation water. Terbacil phytotoxic residues persisted in the upper 15 cm of a silty clay loam soil 16 months after treatment with terbacil at 6.7 kg/ha (Morrow & McCarty, MRID 05013593). Terbacil phytotoxic residues persisted in the upper 8 cm of a silty clay loam soil 4 months after application of terbacil at 1.1, 3.4, or 6.7 kg/ha. Phytotoxic residues were found in the upper 10 cm of a sandy loam soil 1, 3, and 5-6 months after application of terbacil at 0.25, 0.50, and 1.00 kg/ha, respectively (Rahman, MRID 05013219). Increasing soil organic matter content tended to reduce herbicidal activity. No terbacil phytotoxic residues were found 6 months after application in any of the soils (ranging in texture from sand to peat) treated with terbacil at 0.25 kg/ha.

Only 20% of the terbacil applied at 2.24 and 4.48 kg/ha/year for three consecutive years to a sandy soil persisted for 1 year following each of the last two applications (Skroch et al., 05013212). Average terbacil levels ranged from 0.41 to 0.73 lb/A in the upper 18 inches of fine sand soils which had received multiple applications of terbacil at 4-20 lb/A over a 2-5 year period (Tucker & Phillips, MRID 05017207). Terbacil was mobile in these soils to 18 inches (maximum depth sampled).

Terbacil phytotoxic residues persisted in orchard soils for ≥1 year after the last of five annual applications of terbacil at 1.6 lb ai/A (Benson, MRID 05020698). Terbacil phytotoxic residues appeared to be mobile in the soils to depths of 18-24 inches. The phytotoxic effects were greatest in the sandiest soil, indicating that deactivation may occur in the finer textured soils. However, terbacil, applied in three consecutive annual applications at 1-2 lb ai/A, was persistent in a muck soil. Terbacil and 3-tert-butyl-5-chloro-6-hydroxymethyluracil (a degradation product) were found at 0.6 and 0.3 ppm, respectively, in muck soil samples collected 2 years after the last application. Terbacil persisted at phytotoxic levels in the upper 15 cm of a clay loam soil for >2 years after the last of four annual applications of terbacil (80% wettable powder) at 2.24 kg/ha (Doughty, MRID 05013351). In the upper 15 cm of a silt loam soil, terbacil residues dissipated to nonphytotoxic levels 1 year after the last of two annual applications at 4.48 kg/ha.

Terbacil was not taken up (<0.04 ppm) by crops (beet, sunflower, and cabbage) grown in a greenhouse on a silt loam soil 1 year after the last terbacil treatment at 2 lb ai/A (DuPont, MRID 00011948; Holt & Pease, MRID 00011949). Terbacil was present at 0.18 ppm in cabbage grown in a muck soil sampled 2 years after the last application at 1-2 lb ai/A, but terbacil was not detected in beet roots or tops or sunflower seeds. For at least 2 years following an application of terbacil at >1 lb/A, organic soils may retain residual terbacil that would be available for uptake by rotational crops. This is not expected to pose a problem because terbacil is not presently used on crops grown in rotation with other crops.

[^{14}C]Terbacil did not accumulate to high levels in bluegill sunfish (Lepomis macrochirum) exposed at 0.01 and 1.0 ppm over 4 weeks (Rhodes, MRID 00011947). Maximum accumulation factors were 2, 6, and 11 for edible tissues and heads, livers, and viscera, respectively. Levels of ^{14}C residues in all tissues declined to negligible levels within 3 days during the depuration period. Terbacil was stable in both aqueous solutions and fish tissues over the test period, accounting for >99% of the radioactivity of all samples.

These data showing terbacil stable in water (pH 7.0) at 19°C are in agreement with the hydrolysis data. However, they appear to be in conflict with the results of the phtolysis studies.

In summary, terbacil was stable to hydrolysis at pH 5, 7, and 9 at 15°C, but undergoes photodegradation in water with a half-life of 1 month. Photodegradation was accelerated in the presence of a photosensitizer. Nitrification and nitrifying bacteria are inhibited while soil respiration and nitrogen mineralization were generally unaffected by terbacil at concentrations much

higher than recommended use rates (0.5-10 lb/A). Due to its leaching behavior, terbacil shows a potential to contaminate ground water particularly below sandy soils. Leaching may be slower in finer textured soils and soils having higher organic matter contents. Terbacil (≤8 ppm) had a half-life of 2-5 months in aerobic soil, whereas in anaerobic soil, degradation was extremely slow. In the field, terbacil phytotoxic residues persist in soil for up to 16 months following a single application of terbacil. Phytotoxic residues resulting from multiple applications of terbacil persisted for 2 year following final application. The dissipation of terbacil in soil was apparently a function of rainfall, soil charcteristics, and application rate. Terbacil may be available for uptake by rotational crops; however, terbacil is not presently applied to crops which are grown in rotation with other crops. Terbacil does not accumulate to significant levels in fish.

Recommended Label Restriction

Terbacil should not be applied to sandy soils, particularly if the water table is near the soil surface.

C. Environmental Fate - Manufacturing-use Terbacil

1. Degradation

Hydrolysis

^{14}C-Terbacil at 5 ppm was stable (>2% water was degraded) in buffered aqueous solutions at pH 5, 7, and 9 for at least 6 weeks at 15°C (Rhodes, MRID 0001196).

Available data partially fulfills the data requirements in Section 163.161-1 by providing information on the hydrolysis of terbacil in buffered aqueous solutions at acidic, neutral, and basic pHs at 15°. An additional study at 25°C as specified in Section 163.161-1 is needed to fully assess the hydrolysis of terbacil.

Photodegradation in Water

^{14}C-Terbacil in aqueous solution had a photolytic half-life of about one month. Four weeks of irradiation with UV light (300-400 mn, 1,500 uW/cm^2) resulted in degradation of about 16% of the applied ^{14}C-terbacil (5 ppm) in distilled water (pH 6.2), 50% in standard reference water (pH 8.1; equivalent of an average or typical surface water in the United States, (Freeman. 1953. Sewage Ind. Wastes 25:845), 27% in natural river water, and >99% in standard reference water with the photosensitizer riboflavin. The photodegradation products were

5-chloro-6-methyluracil
3-tert-butyl-6-methyluracil
3-tert-butyl-5-chloro-6-hydroxymethyluracil
6-chloro-2,3,dihydro-3,3,7-trimethyl-5H-oxazolo(3,2-a)-pyrimidine-5-one
and two polar compounds.

In standard reference water and river water (pH 6.5), about 50-60% of the applied ^{14}C-terbacil (5 ppm) was degraded under natural sunlight in four weeks; 99% was degraded in standard reference water with riboflavin. The photodegradation products were 5-chloro-6-methyluracil, 3-tert-butyl-6-methyluracil, and an unidentified compound (Rhodes, MRID 00011946).

Under sunlight, terbacil (chromatographically pure) at 700 ppm was photodegraded in slightly alkaline aqueous solutions containing methylene blue or riboflavin as a photosensitizer. The half-life of terbacil with either sensitizer at 35-38°C and at pH 7.8 was $\leq$2 hours. No degradation occurred under acidic conditions (pH 3-6.8) using methylene blue as the sensitizer. The degradation rate of terbacil with and without sensitizer decreased with decreasing pH and temperature. The major photodegradation product was 3-tert-butyl-5-acetyl-5-hydroxyhydantoin. This compound was deacylated by nonphotochemical processes at >15°C and pH $\geq$7.8 to yield 3-tert-butyl-5-hydroxyhydantoin. In acidic solutions (pH 3-6.8; wth riboflavin as a sensitizer) under sunlight, a mono-N-dealkylated dimer and an unidentified oligomer were formed. The addition of humic acid had no effect on the degradation of terbacil irradiated with a mercury lamp (400-700 nm) (Acher, MRID 000390011).

Available data fulfill the data requirements in Section 163.161-2 by providing information on the photolysis of terbacil in water with and without photosensitizers at pH 3.0-9.2.

Photdegradation on Soil

Available data concerning photodegradation of terbacil on soil were reviewed; however, no valid data are available. Therefore, all data specified in Section 163.161-3 are needed to assess the photodegradation of terbacil on soil.

Photodegradation in Air

Data on the photodegradation of terbacil in the air are not required because terbacil is considered to be non-volatile.

2. Metabolism

Data on metabolism are required to determine the nature and availability of pesticide residues to rotational crops and to help in the assessment of potential disposal and reentry hazards.

Aerobic Soil

In a study conducted in a greenhouse, ^{14}C-terbacil at 2 ppm was degraded in sandy loam (56% sand, 29% silt, 15% clay, 1.4% organic matter, pH 5.6, CEC 4.8 meq/100 g) and silt loam (5% sand, 64% silt, 31% clay, 4.0% organic matter, pH 5.0, CEC 23.4 meq/100 g) soils with half-lives of two and three months, respectively (Rhodes, 00011946). Three unidentified metabolites were isolated, one of which accounted for 2-41% of the applied ^{14}C in both soils. Terbacil at 8 ppm was degraded in a loam soil with a half-life of

approximately five months at 31°C (Zimdahl, MRID 005012290). Another study found that about 80% of the terbacil (80% WP) applied at 100 ppm to sandy loam soils (71% sand, 13% silt, 16% clay, 1.6% organic carbon, pH 6.1, CEC 21 meq/100 g; 65% sand, 17% silt, 18% caly, 3.7% organic carbon, pH 4.8, CEC 36 meq/100 g) persisted for 32 weeks (Marsh and Davies, MRID 05013201).

After irradiation with UV light (wavelengths unspecified) for 546 hours over a period of 6.5 weeks, 58% (38% as terbacil) of the radioactivity applied as ^{14}C-terbacil at 4.5 lb ai/A to a silt loam soil remained (Gardiner, MRID 00012208). The major identified degradation product was $^{14}Co_2$, which accounted for 32% of the applied radioactivity. Approximately 1, 15, and 28% of the ^{14}C-terbacil applied at 2.88 ppm to a sandy loam soil degraded to CO_2 in 28, 330, and 600 days, respectively (Wolf, MRID 05024336, 05013204; Wolf and Martin, MRID 05016176). The addition of organic materials to soil increased the rate of degradation.

Thus, terbacil at normal application rates (2-8 ppm) had a half-life of two-five months in soils ranging in texture from sandy loam to silt loam.

All data specified in Section 163.162-1 are needed to assess the aerobic soil metabolism of terbacil.

Anaerobic Soil

Slight degradation (<5%) of terbacil occurred over a period of 60 days in sandy loam (56% sand, 29% silt, 15% clay, 1.4% organic matter, pH 5.6, CEC 4.8 meq/100 g) and silt loam 5% san, 64% silt, 31% clay, 4% organic matter, pH 5.0, CEC 23.4 meq/100 g) soils maintained under anaerobic conditions (Rhodes, MRID 00011946). The soils were treated with ^{14}C-terbacil at 2.1 ppm and aged (aerobically) in a greenhouse for 30 days prior to establishing the anaerobic conditions.

Only trace amounts of ^{14}C-terbacil, applied at 2.88 ppm, were degraded to $^{14}CO_2$ after 145 days in anaerobic sandy loam soil (Wolf MRID 05024336, 05013204; Wolf and Martin, MRID 05013204). The addition of organic amendments (straw or cornstalks) to the soil had no effect on the rate of terbacil degradation as determined by $^{14}CO_2$ evolution under anaerobic conditions.

All data specified in Section 163.162-2 are needed to assess the anaerobic soil metabolism of terbacil.

Anaerobic Aquatic

Data on anaerobic aquatic metabolism are not required because there are no registered aquatic uses for terbacil.

Aerobic Aquatic

Data on aerobic aquatic metabolism are not required because there are no registered aquatic uses for terbacil.

3. Microbiological

The requirement for the submission of microbiological data is currently being reserved.

Effects of Microbes on Pesticides

^{14}C-terbacil at 2 ppm was slowly metabolized by microbes in soil. At least 90% of the applied ^{14}C remained as ^{14}C-terbacil after 90 days of incubation in both sterile and nonsterile soils. Small amounts (0.8-1.5% of applied ^{14}C) of CO_2 were evolved from nonsterile soil, whereas 0.01% was evolved from sterile soil (Rhodes, MRID 00011946).

Three saprophytic soil fungi (Stachybotrus chartarum, Hendersonula toruloidea, and Epicoccum nigrum) did not produce $^{14}CO_2$ from 2-^{14}C-terbacil (5.33 ppm) during an 8-week incubation period (Wolf, MRIDs 05024336 and 05013204).

Effects of Pesticides on Microbes

Terbacil "pure compound" at 220-630 ppm inhibited soil nitrification and the growth of nitrifying bacteria (Nitrosomonas and Nitrobacter) in soil and in culture (Ratnayake and Audus, MRID 05013602). Terbacil, at 220-630 ppm in soil solutions, inhibited nitrate and nitrite formation by 50%. Terbacil 80% WP at 100 ppm had little or no effect on the O_2 uptake by microorganisms in two sandy loam soils but slightly stimulated (-25%) nitrogen mineralization and CO_2 evolution (Marsh & Davies, MRID 05013201). Technical grade terbacil at concentrations up to 250 ppm had no effect on oxygen consumption in clay and sandy loam soil (Liu & Cibes-Viade, MRID 05015406). 2-^{14}C-terbacil at 2.88 ppm had no effect on $^{14}CO_2$ evolutions in a sandy loam soil Wolf, MRID 05024336, 05013204).

Paper discs treated with terbacil at 20 ug/disc did not inhibit the growth of Chlorella pyrenoidosa or Bacillus subtilis (Thomas, MRID 05018549). Growth of a Pseudomonas sp. and its parasite, Bdellovibrio bacateriovorus, was not inhibited by terbacil (WP) at 2 mg/disk (Wehr & Klein, MRID 05015407).

Activated Sludge

No data are available on the activated sludge metabolism of terbacil.

4. Mobility

Leaching

^{14}C-terbacil, applied at the equivalent of 2 lb. ai/A, was mobile in 18-inch columns of a sandy loam soil (56% sand, 29% silt, 15% clay, 1.4% organic matter, pH 5.6, CEC 4.8 meq/100 g) but was comparatively less mobile in a silt loam soil (5% sand, 64% silt, 31% clay, 4% organic matter, pH 5.0, CEC 23.4 meq/100 g) (Rhodes, MRID 00011946). Approximately 64 and 0.4% of the applied radioactivity was eluted from unaged sandy loam and silt loam soil columns, respectively, leached with 20 inches of water. About 52 and 4% of the applied radioactivity aged in sandy loam and silt loam soils leached from the

respective columns in a degradates leaching study. Only 3-6 and 6-7.5 inches of water were necessary to elute detectable amounts of radioactivity from the aged and unaged soil columns, respectively. However, the distribution of radioactivity in the column was not determined. Terbacil was mobile in a fine sandy soil (Mansell, MRID 05017061). After application of ^{14}C-terbacil at 1 ppm followed by an equivalent of 16.6-20 acre-inches of a 0.01 M $CaSO_4$ solution, 73 and >90% of the applied radoactivity eluted from the 30-cm columns filled with soil collected at the 0-10 and 33-76 cm depths, respectively. Terbacil phytotoxic residues were mobile to depths of 27.5-30 cm in a sandy soil column treated with terbacil (80% WP) at the equivalent of 5.6 kg/ha and eluted with 10 or 20 cm of water (Marriage, MRID 05013202).

A mixture of technical grade terbacil (97% pure) and ^{14}C-terbacil were negligibly adsorbed to sand, sandy loam, sandy clay loam, and silty clay loam soils; see Table 1 for soils characteristics (Davidson, MRID 05014424; Rao & Davidson, MRID 05008371). The Freundlich adsorption K values for the respective soils were 0.12, 0.38, 0.38, and 2.46. ^{14}C-Terbacil was not readily adsorbed (2-13%) to soils ranging in texture from loamy sand to clay. Terbacil adsorbed (54%) readily to a muck soil (36% organic matter) [Liu, MRID 05014175).

Thus, terbacil and terbacil soil aged residues appear to be mobile in most soils. Mobility was lessened in finer textured soils and soils with high organic matter content.

Laboratory Volatility

Although there are orchard and field crop uses for terbacil, this data requirement can be waived based on the chemical and physical properties and the pattern of use of terbacil.

Field Volatility

Although there are orchard and field crop uses for terbacil, this data requirement can be waived based on the chemical and physical properties and the use pattern of terbacil.

Table 1. Characteristics of soils used in terbacil leaching studies.

Soil	Sand (%)	Silt (%)	Clay (%)	pH	CEC (meq/100 g)	Organic Carbon (%)
Webster silty clay loam	18.4	45.3	38.3	7.3	54.7	3.9
Cecil sandy loam	65.8	19.5	14.7	5.6	6.8	4.7
Glendale sandy clay loam	50.7	16.4	22.9	7.4	34.8	3.7
Eustis fine sand	93.8	3.0	3.2	5.6	5.2	4.7

From Davidson et al. (05014424) and Rao and Davidson (05008371).

5. Dissipation

Terrestrial Field Dissipation

Data from field dissipation studies showed that ^{14}C-terbacil dissipated rapidly from a silt loam soil (9% sand, 70% silt, 21% clay, 2.3% organic matter, pH 5.4, CEC 8.9 meq/100 g) contained in 4- x 15-inch cylinders in the field with a half-life of one-two months (Rhodes, MRID 00011946). Dissipation appeared to be due largely to leaching. Terbacil residues were mobile to depths of 12-15 inches (maximum depth sampled) after receiving 18.3 inches of rainfall over a four-month period. ^{14}C residues persisted for at least one year in 4- x 12-inch cylinders driven into a silt loam soil treated with ^{14}C-terbacil (<98% pure) at 4 lb/A (Gardiner, MRID 005002415, 00012031 and 00012032). The radioactive residues were mobile to 12 inches (maximum depth sampled). Approximately 14% of the applied radioactivity remained in the upper 12 inches of the treated soil one year after treatment. 5-Chlorouracil, a suspected degradation product, was not detected in the 0-1 and 8-12 inch soil segments of the five- and fourteen-week samples.

Terbacil at 4.5 kg/ha was mobile in a sandy soil (Mansell, MRID 05014421, 05017062). Terbacil was present at $\leq$100 ppb in subsurface drainage water samples (collected at a depth of 107 cm) after the plot received a total of 18.4 cm of water. Between 0.5 and 1.8% of the applied terbacil leached to 107 cm; therefore, a potential exists for ground water contamination beneath sandy soils treated with terbacil, particularly when deep tillage cultural practices are employed.

One study reported >80% of the terbacil applied at 2.24 and 4.48 kg/ha/year for three successive years dissipated from a sandy soil (80.5% sand, 11.9% silt, 7.6% clay, 0.7% organic matter) within one year following each of the last two applications (Skroch et al., MRID 05013212). Average terbacil levels ranged from 0.41 to 0.73 lb/A in the upper 18 inches of fine sand soils which had received multiple applications of terbacil at 4-20 lb/A over a 2-5 year period (Tucker and Phillips, MRID 05017207). However, a decline curve for terbacil could not be quantitatively determined because soil samples were only collected once at 2, 11 or 13 months after the last application. Terbacil was mobile in these soils to 18 inches (maximum depth sampled).

Using a bioassay method, terbacil dissipated from a clay soil (44.9% clay, 4.5% organic matter, pH 6.4, CEC 43.1 meq/100 g) planted to sugarcane (Liu, MRID 00017711). Thirteen months after application of terbacil at 2-16 lb/A, terbacil phytotoxic residues were detected at 0.01-0.4 ppm in the upper 12 inches of soil, indicating more than 90% dissipation. Terbacil, applied on a silty clay soil (50% clay, 39.5% silt, 10.5% sand, 1% organic matter pH 7.8) at 1.2 and 2.4 lb/A, persisted at levels that were phytotoxic to cotton and sorghum 7 months after treatment (Isom, MRID 00028135, 05018594). These results were observed following an intervening crop and the application of 64 acre-inches of irrigation water. Terbacil phototoxic residues persisted in the upper 15 cm of a silty clay loam soil (2.5% organic matter) 16 months after treatment with terbacil at 6.7 kg/ha (Morrow and McCarty, MRID 05013493). Terbacil phytotoxic residues were found in the upper 10 cm of a

sandy loam soil one, three, and five-six months after application of terbacil at 0.24, 0.50, and 1.00 kg/ha, respectively (Rahman, MRID 050113219). Increasing soil organic matter content tended to decrease herbicidal activity. No phytotoxic terbacil residues were found six months after application in any of the soils (ranging in texture from sand to peat) treated at 0.25 kg/ha.

Terbacil phytotoxic residues persisted in orchard soils (Table 2) for at least one year after the last of five annual applications of terbacil at 1.6 lb ai/A (Benson, MRID 05020698). Terbacil phytotoxic residues appear to be mobile in the soils to depths of 18-24 inches. The phytotoxic effects were greatest in the sandiest soil, indicating that deactivation may occur in the finer textured soils. Terbacil phytotoxic residues persisted in the upper 15 cm of a clay loam soil (30% clay, 3% organic matter, pH 4.7, CEC 30 meq/100 g) for over 2 years after the last of four annual applications of terbacil (80% WP) at 2.24 kg/ha (Doughty, MRID 05013351). In the upper 15 cm of a silt loam soil (17% clay, 12% organic matter, pH 4.7, CEC 56 meq/100 g), terbacil residues had dissipated to nonphytotoxic levels one year after the last of two annual applications at 4.48 kg/ha.

Thus, terbacil residues can persist in soil for 6-16 months following a single application of terbacil at 1-6.7 kg/ha. Multiple applications of terbacil at 2.24 kg/ha can persist for two years following the final application. These studies also indicated that terbacil was mobile in soil to depths of 15-170 cm.

Table 2. Orchard soil characteristics at various depths.

	soil depth (inches)			
Orchard	0-6	6-12	12-18	18-24
		Organic matter (%)		
A	1.3	0.5	0.5	0.5
B	1.3	0.6	0.3	0.3
C	1.1	0.6	0.5	0.4
D	4.9	1.6	0.3	0.3
		Silt and clay (%)		
A	59.6	60.2	63.0	71.6
B	18.9	18.1	17.0	18.9
C	40.8	39.6	35.2	34.0
D	36.6	27.0	18.5	15.5
		CEC (meq/100 g)		
A	11.7	11.7	12.2	13.3
B	11.3	7.6	7.2	7.2
C	11.7	11.3	11.3	11.7
D	15.6	8.9	7.0	5.4

Adapted from Benson (05029698).

Field Dissipation: Aquatic and Aquatic Impact

Data are not required on the aquatic field dissipation of terbacil because there are no registered aquatic or aquatic impact uses for terbacil.

Dissipation: Forestry

Data are not required on the dissipation of terbacil in forests because there are no registered forestry uses for terbacil.

Dissipation: Combination and Tank Mixes

Data requirements for combinations and tank mixes containing terbacil are not cited because this standard covers only the single active ingredient.

Dissipation: Long Term

Data are not available on the long-term dissipation of terbacil. All data specified in Section 163.164-5 are needed to assess the long-term soil dissipation of the manufacturing-use product.

Confined Accumulation: Rotational Crop

Beets (roots and tops), sunflower seeds, and cabbage grown in a greenhouse in a silt loam soil one year after the last terbacil treatment at 2 lb ai/A contained no detectable residues of terbacil (<0.04 ppm) (DuPont, MRID 00011948; Holt and Pease, MRID 00011949). Terbacil was present at 0.18 ppm in cabbage grown in a muck soil sampled 2 years after the last application at 1-2 lb ai/A, but terbacil was not detected in beets or sunflower seeds. For at least two years following the last application, organic soils may retain residual terbacil that would be available for uptake by rotational crops.

No data on the confined accumulation of terbacil is required because the use pattern indicates that terbacil is used on crops which are not grown in rotation with other crops.

Field Accumulation: Rotational Crops

Data on the field accumulation of terbacil in rotational crops are not required because the use pattern indicates that terbacil is used on crops which are not grown in rotation with other crops.

Accumulation: Irrigated Crops

Data are not required on the accumulation of terbacil in irrigated crops because there are no registered uses for terbacil on irrigation ditchbanks.

Fish Accumulation: Laboratory Studies

^{14}C-Terbacil did not accumulate to significant levels in bluegill sunfish (Lepomis macrochirus) (Rhodes, MRID 000119447). Average residues of terbacil were 0.11 and 7.9 ppm in viscera, 0.02 and 1.8 ppm in heads, 0.07 and 4.4 ppm in livers, and 0.02 and 1.7 ppm in edible tissues of bluegill sunfish exposed

at 0.01 and 1.0 ppm, respectively, over four weeks. Levels of ^{14}C residue in all tissues declined below detection limits (0.01 ppm) during the depuration period. Terbacil residues in edible tissues declined from 0.02 and 2.2 ppm on day 28 of the exposure period to <0.01 on day 3 of the depuration period for 0.01 and 1.0 ppm exposure levels, respectively. Terbacil was stable in both aqueous solutions and fish tissues over the test period, accounting for >99% of the radioactivity of all samples.

Field Accumulation: Aquatic Non-Target

Data are not required on the accumulation of terbacil in aquatic non-target organisms becuase there are no registered forestry, aquatic non-crop, or aquatic impact uses for end-use products of terbacil that result in direct discharges.

7. Re-entry

Re-entry data may be required to support the registration of manufacturing-use and end-use terbacil. Requirements will be decided on a case-by-case basis.

D. Exposure Profile - Terbacil

Terbacil is a substituted uracil herbicide registered for the control of certain perennial grasses and annual weeds in sugarcane, apples, alfalfa, peaches, pecans, ornamentals, berries, citrus, and mint. Approximately 400,000-800,000 pounds of active ingredient are applied annually; about 75% is applied to sugarcane in Louisiana and Texas, and another 14% is applied to apples. Terbacil is formulated as an 80% wettable powder which is applied, depending on site and equipment availabilty, aerially or by high-volume ground rig sprayers.

1. All Formulations

Data are not available to fully assess the potential for exposure of humans and non-target organisms including wildlife to terbacil. Available data indicate that terbacil leaches in most soils (Davidson, MRID 05014424; Mansell, MRID 05014421, 05017062 & 05017061; Marriage, MRID 05013202; Rao & Davidson, MRID 05008371; Rhodes, MRID 0011946). Therefore, the potential for ground water contamination exists. Contamination of surface waters in proximity to terbacil-treated areas and subsequent exposure of humans and non-target organisms is also possible due to terbacil's mobility in soil and high water solubility at 710 ppm at 24°C (Weed Sci. Soc. Am. 1979, MRID 003900140).

Beet (roots and tops), sunflower (seeds), and cabbage grown in the greenhouse on a silt loam soil treated with terbacil at 2 lb ai/A 1 year earlier contained no detectable residues of terbacil (<0.04 ppm) (Dupont, MRID 00011948; Holt & Pease, MRID 00011949). Terbacil was present at 0.18 ppm in cabbage grown in a muck soil sampled 2 years after the last application at 1-2 lb ai/A, but no terbacil was detected in beet or sunflower seeds. Therefore, organic soils may retain residual terbacil for up to 2 years following the

last application that would be available for uptake by rotational crops. However, this is not expected to be a problem because terbacil is not used on crops grown in rotation with other crops. (U.S. EPA, 1981). Average residues of terbacil were 0.11 and 7.0 ppm in viscera, 0.02 and 1.8 in heads, 0.07 and 4.4 ppm in livers, and 0.02 and 1.7 ppm in edible tissues of bluegill sunfish (Lepomis macrochirus) exposed at 0.01 and 1.0 ppm, respectively, over 4 weeks (Rhodes, MRID 00011947). Levels of radiolabeled residues in all tissues declined below detection limits (0.01 ppm) after depuration for 3 days. Therefore, terbacil does not appear to accumulated to significant levels in fish.

Human exposure to terbacil during mixing and application of the formulated product and to dislodgeable plant residues cannot be assessed due to the lack of available data. Exposure is expected to be greatest during mixing and application of the formulated product and would result primarily in respiratory ("puff back") exposure. Respiratory exposure could be minimized by wearing an approved respirator. Dermal and ocular exposures could be minimized by the use of gloves, goggles, and other protective clothing while terbacil is being handled. Spray drift as a result of aerial applications of terbacil may occur; however, data to assess such exposures are not available.

E. Summary of Data Gaps

The major data for terbacil are hydrolysis studies, phtolysis studies on soil, aerobic and anerobic soil metabolism studies, leaching studies, and terrestrial and long-term field dissipation studies.

Chapter VI

Toxicology

A. Toxicology Profile

1. Acute Effects

Although available data are sufficient to characterize terbacil as of a low order of acute toxicity, no acceptable data on acute studies are available. These acute studies were conducted using the 80% wettable powder formulation. These studies should be repeated using terbacil technical chemical. No data are available to assess the acute inhalation toxicity of terbacil. Supplementary data are available to assess the primary eye and dermal irritation and dermal sensitization of terbacil.

2. Subchronic Effects

Essentially the only toxicity in evidence in the 90-day feeding study with terbacil is increased liver weight and liver/body weight ratio. In the 10-dose subchronic study in which terbacil was administered via intubation (1000 mg/kg), acute behavioral symptoms were observed which were not evident in the 90-day feeding study (high dose 250 mg/kg), in addition to transient histologic changes in the liver. However, no mortalities were observed at this level, which was 4 times the highest level fed in the chronic toxicity study. The subchronic dermal toxicity study lends further evidence of the low dermal toxicity of terbacil. Because of insufficient dose levels and other reporting inadequacies, the study should be repeated in accordance with the Guidelines.

A subchronic toxicity study in a second (non-rodent) species is required. However, since a 2-year chronic dog feeding study has been conducted and found acceptable, this 2-year chronic dog feeding study will aso satisfy the non-rodent requirements of a subchronic feeding study.

3. Chronic Effects

In both the rat and dog chronic feeding studies, increased actual and relative liver weights were the only changes observed which could be attributed to terbacil. The NOEL for the dog is 50 ppm and in the rat 250 ppm. The rat study also failed to produce any evidence of oncogenicity. An oncogenicity study in a second species is still required. The three-generation reproduction study in rats must be repeated due to study design and audit deficiencies. Concerning teratogenicity, the apparent positive results (hydronephrosis) in the evaluated study must be further investigated in an additional post-natal study in the rat or it must be adequately demonstrated to the Agency that these findings are within the normal ranges in other studies conducted. A complete final report with individual rather than summary data is needed in order to provide adequate data for evaluation. In addition, another teratology study in a second species is required.

B. Manufacturing-use Terbacil

1. Acute Effects

Available data are not acceptable to assess the acute oral and dermal toxicity of technical terbacil. Data on the acute inhalation toxicity of technical terbacil are not available.

Primary Eye Irritation

In a primary eye irritation study in rabbits, the test material was not properly identified as terbacil. In the study the chemical was administered as a powder or a 10% suspension in propylene glycol, instilled in two pairs of rabbit eyes. One eye of each pair was washed for one minute, 20 seconds after instillation. Terbacil was mildly irritating to the rabbit eye, both as a suspension and as a powder. As a powder it caused mild conjuctival redness and swelling through 4 hours in the unwashed eyes only. As a suspension it caused transient injection of iritic blood vessels in the unwashed eye and mild conjunctival inflammation in both eyes. There was no coreal injory at any time (DuPont, MRID 0039006).

This study provides supplementary information on the eye irritation potential of terbacil since it used an insufficient observation period, too few animals, and the test animals' eyes were not scored. A complete standard primary eye irritation study sould be conducted.

Primary Dermal Irritation and Sensitization

One study provided summary data on a combined dermal irritation and sensitization study in 10 albino guinea pigs. Irritation tested by application of terbacil purified chemical dissolved in 1:1 acetone:dioxane containing 13% guinea pig fat to intact skin at a concentration of 15% gave negative observations for irritation at both days 1 and 2. Observations were made for only 72 hours. This study provides supplementary data (DuPont, MRID 0039007).

In the sensitization portion of the studies, guinea pigs were not sensitized. Half of each group received applications on abraded skin and the remainder received intradermal injection (1% terbacil in propylene glycol) and were challenged by application on intact and abraded skin after two weeks and repeated two weeks later. This study provides supplementary data and should be repeated.

2. Subchronic Effects

90-Day Subchronic Feeding in Rats

A 90-day subchronic feeding study in rats using terbacil wettable powder formulation gave a NOEL of 500 ppm active ingredient terbacil. Female rats at the 5000 ppm dose gained slightly less weight (about 15%) than the control females, although treated females at this dietary level essentially paralleled

the control males in body weight gain at all times. The only other significant effect was an increase in actual and relative liver weights of males and females at the 5000 ppm dosage level. The increased liver weights were accompanied by a moderate to marked hypertrophy of hepatic parenchymal cells associated with vacuolation of scattered herpatocytes (International Research & Dev., MRID 00039009).

This study provides minimum data and fulfills the requirements of a 90-day subchronic oral toxicity study.

10-Dose Oral Subchronic Toxicity in Rats

In a 10-dose oral subchronic toxicity study, 6 young male and female Chr-CD rats were each administered, by gastric intubation, 1000 mg/kg of terbacil technical in the form of a 10% aqueous suspension of the 80% wettable powder formulation, 5 times a week for 2 weeks. Three of the test rats, along with controls, were killed 4 hours after and 3 were killed 14 days after the last treatment. Some acute toxic signs were observed during treatment (including inactivity, incoordination and salivation). However, no toxic signs were observed during the 14-day recovery period (DuPont, MRID 00039005).

Pathologically, after the 10th dose, liver weights and liver/body weight ratios were greater than those of control animals, but there was some evidence of remission after the 14-day recovery period. Histologic changes attributable to the compound were confined to the livers of the test animals sacrificed soon after the 10th dose. These included slight liver cell enlargement in the centrilobular area, margination of the larger cytoplasmic contents to the cell membrane, and increased mitotic activity. No significant lesions attributable to the compound were found in any other tissues.

Subchronic Dermal Toxicity in Rabbits

Five g/kg terbacil technical chemical was applied as a 55% aqueous paste of the wettable powder formulation to the dorsal clipped abraded torsos of 5 male and 5 female albino rabbits, 5 days weekly for 3 weeks. There were no pathologic changes, gross or microscopic, that could be attributed to terbacil. Also, no clinical signs of toxicity were observed. Organs and organ/body weight ratios were comparable to controls (DuPont, MRID 00012235).

This study provides supplementary information and should be repeated because insufficient dose levels were used and a complete study report was not available.

3. Chronic Effects

Chronic Feeding and Oncogenicity Study in Rats

A 2-year chronic feeding study in rats used the 80% wettable powder formulation and gave a NOEL of 250 ppm. (Dosing was based on active ingredient.) Male and female rats at the high (2500-10,000 ppm) dietary level exhibited a lower rate of body weight gain as compared to the controls. The only compound-related variation in organ weights was a slight increase in

liver weight among rats from the high (2500-10,000 ppm) level sacrificed after 2 years on study. There was no indication of any compound-related oncogenic effect at any dietary level (International Research & Development Corp., MRID 0039001). This study provides minimum data and satisfies the requirement of a chronic feeding and oncogenicity study in rats.

Two-Year Chronic Feeding Study in Dogs

A 2-year subchronic feeding study in beagle dogs using terbacil 80% wettable powder formulation gave a NOEL of 50 ppm active ingredient terbacil. Neutropenia and leucocytosis occurred in 1 female at 1 month and 24 months at the 250 ppm dietary level. No unusual alterations in behavior and appearance, body weigh gains, food consumption, water intake, urine output, hematology, plasma biochemistry, liver function tests, or urinalysis were observed. No compound-related gross or microscopic pathologic changes were seen in any of the dogs sacrificed after 1 and 2 years of compound feeding, except for a slight increase in relative liver weight in dogs at the high (2500-10,000 ppm) dose group which were sacrificed at 1 and 2 years. (NOTE: the upper dietary level was periodically increased from the 26th to the 46th week of the study to a final concentration of 10,000 ppm. International Research & Development Corp., MRID 0039002).

Oral Teratology in Rats

Terbacil technical chemical was administered in the diet at levels of 0, 250, 1250, and 5000 ppm active ingredient to 27 female rats per group during days 6 through 15 of gestation. On day 21 all rats were sacrificed by chloroform inhalation. Uterus and ovaries were removed and inspected for gross changes. The uterus was then opened and the fetuses removed and examined (DuPont, MRID 00039).

At doses of 1250 and 5000 ppm, rats exhibited a dose-related reduction in mean body weight when weighed on days 10, 16 and 21 of gestation. The 250 ppm dietary level did not significantly alter the mean body weight of pregnant rats. This study demonstrates an apparent dose-related effect on implantation, with the number of implantations per litter declining with increasing dosage. Since dosing was to be initiated after implantation, there should be no compound effect on implantation. It would therefore appear the compound was administered to these animals prior to implantation, interfering with this process. These study findings (apparent effect on implantation) confound conclusions reached on the potential fetotoxic effects of the compound; for example, the number of live fetuses per litter is also reduced at all dose levels and it is not possible to ascertain whether this is actually compound-related or not.

Retarded ossification of pubic bones and centra, wavy ribs, and one pair of full 14th ribs were each found in fetuses of 1 to 2 litters in the control group, but not in the test groups. Unossified sternebrae and rudimentary 14th ribs were found in all groups, and no apparent dose relation was noted. Dilatation of the renal pelvis and ureter were found in all test groups, but not in control litters. The teratologic significance of the renal pelvis and ureter dilatations is difficult to assess, particularly since individual animal findings were not submitted with the report. Numerically they are statistically significant and compound-related, although no specific dose response curve is evident. But whether they are true "terata," or whether

they are a result of developmental retardations (fetotoxicity) reversible with growth can be determined only by additional study (a post-natal evaluation in the rat).

It also is noted that individual data were not included in the final report, which limited evaluation and contributes to the conclusion that the study provides only suppplementary data. The findings of dilation of renal pelvis and/or hydroureter observed in the dose groups at significant levels (but not in controls) must be, at this time, considered a teratogenic response. However, it is reconized that after further investigation, i.e. a repeat of this study, preferably via gavage, with an additional post-natal segment) these findings may be attributed to factors other than a teratogenic response, i.e., developmental growth retardations reversible with growth (fetotoxicity) or normal background incidence. Alternatively, if it can be demonstrated with adequate historical data from the testing facility that the hydronephrois found in dosed groups of this study is within normal limits, a repeated study will not be required.

Reproduction

Three-Generation Reproduction in the Rat

In the following study on reproduction, some deficiencies of significance were noted in the conduct of this study during an EPA/FDA audit of the testing laboratory In June 1979. The examined data indicated that it was found necessary to treat animals with respiratory disease. The NOEL for reproductive effects is apparently 250 ppm while the NOEL for systemic toxicity was determined to be 50 ppm.

The test material used in a three-generation reproduction study was the 80% wettable powder formulation at dietary levels of 50 ppm and 250 ppm active ingredient terbacil. No unusual alterations in behavior and appearance which could be related to the feeding of terbacil in the diet were observed in any of the three generations of parental rats in the study. There were effects in body weight gain in males but not in females at 50 and 250 ppm (not significant at 50 ppm). There was an increase in relative liver/body weight ratio at 250 ppm and in absolute mean and relative heart weights in the F_{3b} offspring. Also, no consistent compound-related effects were observed at either test level for litter size, viability, and pup weights at birth. A slight reduction, but not significant, in survival to weaning at 250 ppm was noted as compared to controls (International Research & Development, MRID 0039003).

Pathologically, no compound-related gross lesions were observed in pups from either treated group. Also, no significance could be attached to slight variations in relative mean organ weights between the groups. Furthermore, no compound-related histopathologic lesions were observed in any tissues examined from any of the pups from either treated group.

This study provides core supplementary data due to the study design and additional audit deficiencies noted during the EPA/FDA audit.

Metabolism

Metabolism studies in the laboratory rat as described by Guidelines Section 163.85-1 were not conducted. Metabolism studies in the lactating goat, lactating cow, laying hens, and in rumen fluid and beef liver were considered in the section on residue chemistry. A standard metabolism study, preferably in the laboratory rat, should be conducted in accordance with Guidelines Section 163.85-1.

Mutagenicity

Complete data from mutagenicity studies were not available for evaluation, but one journal article (MRID 05016657), one abstract (MRID 05017208), and a pre-publication manuscript (MRID 00013309) were examined. These all related to gene mutation and indicate terbacil to be non-mutagenic. In addition to a complete study data on gene mutation, it is expected that registrants will be required to provide data from studies to detect primary DNA damage and chromosomal aberrations.

C. Data Gaps

The toxicology data gaps for manufacturing-use terbacil are:

acute oral, dermal and inhalation toxicity
primary eye and skin irritation toxicity
dermal sensitization
subchronic 21-day dermal toxicity
teratogenicity
reproduction
mutagenicity
metabolism

Chapter VII

Residue Chemistry

A. Residue Chemistry Profile

The metabolism of terbacil in plants is adequately understood. The major residues are intact terbacil and metabolites A, B, and C. In plants terbacil is absorbed, translocated and metabolized. Animals also metabolized terbacil. Initially, the significant residue was considered to be terbacil and some tolerances were established on this basis. Terbacil was later found not to be the only component of the residue. At present residue in or on plants resulting from terbacil use is expected to be intact terbacil and metabolites A, B, and C. (Later tolerances were established on this basis.)

Methods for the analysis of terbacil are adequate for the purpose of data collection. The method for terbacil published in the Pesticide Analytical Manual Volume II is not adequate for all enforcement purposes because the method does not detect the three terbacil metabolites that constitute a part of terbacil tolerances.

The reported residue studies overall reflect the registered uses of terbacil on raw agricultural crops and their by-products and feed items. The established tolerances for residues of terbacil or combined residues of terbacil and metabolites A, B, and C, which may result from the registered uses, are found to be adequate for the raw agricultural commodities alfalfa hay and forage, blueberries, mint hay, strawberries and sugarcane. Data are available to support the tolerances for alfalfa seed screenings, asparagus, caneberries, pecan, and sainfoin hay and forage. These conclusions apply to the use of terbacil alone and to terbacil used in combination with diuron.

Feeding studies reflecting residues of terbacil and metabolites A, B, and C in cattle, goats, and poultry were adequate in exhibiting the possible transfer of terbacil to fat, milk, and the meat of cattle, goats, hogs, horses, and sheep.

The individual topical discussion sections in this chapter and the data tables in Chapter III may be referenced for specific information and data requirements.

B. Metabolism in Plants

The metabolism of terbacil in plants and the distribution of absorbed and translocated residue have been adequately studied. Several studies have shown that 5-chlorouracil is not formed as a result of the metabolism of terbacil in plants.

Laboratory studies have shown terbacil to be readily absorbed and translocated by most plants. In sugarcane, 80% of the applied ^{14}C (as uncharacterized terbacil residues) accumulates in the leaves 3 weeks after stem injection with [2-^{14}C]terbacil, whereas only 6.8% and 1.8-3.5% of the applied ^{14}C were found in the cane pulp and juice, respectively (Gardiner, MRID 05002415; Rhodes and Weed, MRID 00012014). Weierich found that terbacil residues were

translocated from the roots to the leaves of pepermint plants grown in [2-^{14}C]terbacil solutions; 21-33% of the total ^{14}C recovered from the plants was found in the leaves after 3 days (MRID 0501494).

When radioactivity was characterized, intact terbacil constituted 22% of the leaf residues, but the identities and amounts of metabolites were not determined. After an additional 11 days in terbacil-free solution, 78% of the terbacil in leaves was either metabolized or translocated. Orange seedlings also absorb terbacil from solution via the roots although only 5-21% was translocated to the leaves and stems over a 2 to 12-week period (Jordan, MRID 0513598). After 9 weeks in a [2-^{14}C]terbacil solution, over 90% of the ^{14}C recovered in all plant parts existed as metabolite A (3-tert-butyl-5-chloro-6-hydroxy- methyluracil) which was conjugated with a carbohydrate moiety through a beta linkage.

An alfalfa field study revealed that [2-^{14}C]terbacil or its soil metabolites are taken up by alfalfa. Intact terbacil accounted for 10.8% of the recovered ^{14}C whereas 3 tert-butyl-5-chloro-6-hydroxymethyluracil, and metabolite A (3-tert-butyl-5-chloro-6-hydroxymethyluracil, metabolite B (6-chloro-2, 3, dihydro-7-hydroxmethyl-3,3-dimethyl-5H-oxazolo- [3-,2-a]pyrimidin-5-one) accounted for 4.8, 10.3, 35.6, and 15.8%, respectively (Rhodes, MRIDS 00011965, 05013216).

The residues in or on plants resulting from terbacil use are expected to be intact terbacil and metabolites A, B, and C. Residues may exist as glycosylated derivatives, and terbacil per se is frequently not the predominant residue species. Should the tolerances be revised to include these metabolites, then the plant metabolism data would not be considered adequate for those crops (apples, citrus fruits, peazches, pear, and sugarcane) for which residues are expressed in terms of terbacil alone.

C. Metabolism in Animals

Terbacil was not degraded when incubated with rumen fluid, chopped beef liver, or the supernatant fraction of homogenized beef liver (Gutemann and Lisk, MRID 05002373).

A lactating nanny goat was fed [2-^{14}C]terbacil at 3.6 ppm for one day. Most of the terbacil ingested was metabolized within 1 day; 85% of the applied radioactivity wazs found in the 0-24 hour urine sample. When urine radioactivity was characterized, 86% of the radioactivity was accounted for as metabolite A (Han, MRID 00011950).

The metabolism of terbacil in animals is considerred to be adequately defined.

D. Analytical Methodology

Pease developed a gas chromatographic (GC) analytical method for terbacil in biological materials. In this method, a 25-g crop sample is blended with 1% NaOH, centrifuged and acidified. Terbacil is extracted from the solution with chloroform. After further treatment, the extract is cleaned up in a Florisil column, eluted with ethyl acetate and determined by microcoulometric gas

chromatography. The sensitivity of this method is 0.04 ppm for a 25-g sample; recoveries range from 85-110% at levels up to 5 ppm. This method detects only terbacil (DuPont, MRIDs 00012181, 00012035, 05012979, 05014422).

An improved GC method, which detects terbacil and three significant metabolites (3-tert-butyl-5-chloro-6-hydroxymethyluracil (metabolite A), 6-chloro-2,3-dighdro-7-hydroxymethyl-3,3-dimethyl-5H-oxazolo-[3,2-a]-pyrimidin-5-one (metabolite B), and 6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo-[3,2-a]-pyrimidin-5-one (metabolite C) in samples of various substrates, is described in reports by Holt and Pease (MRID 00011949, 05015405). For this method, samples (25 g of solid, 50 g of milk, urine, or aqueous solutions) are blended with chloroform, centrifuged, and the organic phase is collected. After further treatment, the extract is derivatized with Regisil-TMCS. After the reaction is complete, the silyl derivative is analyzed by microcolometric gas chromatography. The reported sensitivity of this method is 1.0 ug of each compound, or 0.04 ppm based on a 25-g sample; recoveries range from 45-140%, 40-144%, 41-133%, and 50-130% for terbacil and metabolites A, B, and C, respectively, at levels ranging from 0.04-10.0 ppm. Recovery data for this method are presented in a report by DuPont (MRID 1237).

Cessna (MRID 05013352) described an improved form of the original Pease technique for analyzing terbacil in blueberry. Samples (25 g) are blended with 1% NaOH, extracted with chloroform, and cleaned up in a Florisil column as described before. The Florisil column is eluted with 5% acetone in hexane. The concentrated eluate is then analyzed with electron-capture gas chromatography. The limit of detection is 1 ppb; recoveries range 91-98% at a level of 0.1-1 ppm.

An analytical method for determining terbacil and three metabolites (A, B, and C) in alfalfa by microcoulometric gas chromatography is described in an unpublished study by Holt and Pease (MRID 00011960). This method determines residues in milk and urine samples that were used in an unpublished study submitted by DuPont (MRID 00011961) and the studies by Pease describe verification techniques for this method (MRIDs 00011953, 1235). This analytical method is similar to the method of Holt and Pease which was described previously: extract with chloroform, clean up, derivatize the product and analyze the silyl derivatives (MRID 00011949, 050154505). The sensitivity of this method for terbacil (0.05 ppm for a 25-g sample) is less than that reported in PAM II. This method is also less sensitive for the metabolites (0.05 ppm for 25-g sample) than the method of Holt and Pease.

These analytical methods, as decribed, are adequate as far as they go in determining the indicated components of the residue, and for enforcing the established tolerances for the listed commodities.

E. Residue Data

Field residue data for terbacil should reflect the registered uses with regard to application rate, methods of application, number and timing of applications, formulations used, and the geographical areas represented. Generally, only one terbacil application is made per year, regardless of the site. No preharvest intervals have been established for terbacil-treated crops.

1. Sugarcane

The directions for use of terbacil on sugarcane require a broadcast, band, or directed spray application using wettable powder at 0.4-3.2 lb ai/A. Terbacil may be applied in 5-10 gallons of water/A by air or in at least 40 gallons/A by ground equipment. Use on sugarcane is limited to preemergence weed control in Hawaii, Louisiana, Puerto Rico, and Texas.

In general, treatments must be made before the cane emerges, thus avoiding foliar contact with spray material. Only one annual application is allowed, except in Texas where a spring and a fall application may be made annually. Terbacil should not be used on thinly covered subsoils or rock areas. Treated areas should not be replanted to any crop other than sugarcane or pineapple within 2 years after the last application. A tolerance of 0.1 ppm has been established for residues of terbacil in or on sugarcane.

Two studies showed that terbacil was not detected (<0.04 ppm) in or on raw sugarcane at 181-265 days after the single or second of two applications made at 1.2-4.5 lb ai/A of the 80% wettable powder. Several of the terbacil application rates were equal to or higher than the maximum recommended rate. Field plots for these studies were located in Louisiana. Although cultural practices differ between the continental United States, Hawiaii and Puerto Rico, it is not considered necessary, for preemergence applications, to require data from other locations (DuPont, MRIDs 00121879, 00012180).

Terbacil was not detected (<0.04 ppm in molasses or bagasse samples processed from treated sugarcane. In the absence of data, residues would not be expected to be detected in cane sugar.

Since no terbacil residues were detected (<0.04 ppm), the data support the 0.1 ppm tolerance for terbacil in or on raw sugarcane. The available residue data on sugarcane and the established tolerance reflect the presence of terbacil alone. Should the tolerance be revised to include metabolites, residue data on these components would be needed.

2. Alfalfa

The recommended terbacil application rates for alfalfa are 0.4-1.2 lb ai/A. It is applied as a broadcast treatment to dormant plants or to fields after the final harvest. Ground equipment is used to make the single annual application. Terbacil should not be used on mixed stands or on seedling alfalfa, and should not be applied on snow-covered or frozen ground, or south of Interstate 80 in California. A tolerance has been estabilished for combined residues of terbacil and metabolites A, B, and C in or on alfalfa hay and forage at 5 ppm.

Alfalfa forage treated with [2-^{14}C]terbacil at 1.0 lb ai/A contained combined residues of terbacil and metabolites A, B, and C of 3.04 ppm, 6 months after application. Terbacil was present at 0.44 ppm (Rhodes, MRIDS 00011965, 05013216).

Alfalfa forage treated in the field with terbacil (an unknown formulation, presumably the 80% wettable powder) at 0.4-4.0 lb ai/A contained combined

residues of 0.2-1.21 ppm of terbacil and metabolites A, B, and C 28-458 days after treatment. Terbacil was usually the major residue (DuPont, MRID 00011959).

Residues of intact terbacil were <0.07-1.3 ppm in hay and forage of birdsfoot trefoil 119-252 days after treatment with terbacil at exaggerated rates of 2-8 lb ai/A. Metabolites A, B, and C were not quantified. Birdsfoot trefoil is similar to alfalfa, and residues on one are supportive of residues on the other (DuPont, MRID 00011959).

Since the rates used were within or well exceeded the recommended rates, and all residues were less than the tolerance, the available data support the established tolerance of 5 ppm for alfalfa forage and hay.

3. Blueberries

Terbacil is applied by ground equipment to blueberries as a broadcast, band or directed spray treatment to the ground beneath bushes at 1.6-3.2 lb ai/A. A minimum of 25 gallons of water/A is used. A single application is made annually in the spring or fall. Spray contact with the fruit and foliage must be avoided. A tolerance of 0.1 ppm has been established for combined residues of terbacil and metabolites A, B, and C in or on blueberries.

No detectable residues (<0.04 ppm) of terbacil or metabolites A, B, and C were present in blueberries 55-482 days after treatment with terbacil at 1.6-6.4 lb ai/A. (Rutgers University, MRID 00012039).

A very sensitive technique using a detection limit of 1.0 ppb found that terbacil residues in blueberries were $\leq$2.0 ppb 3 months to 2 years after treatment with terbacil at 0.84-3.36 lb ai/A (either alone or in combination with atrazine, diuron, glyphosate, or paraquat). Metabolites A, B, and C were not quantified (Cessna, MRID 0513352).

The data from Rutgers University support the 0.1 ppm tolerancce for combined residues of terbacil and metabolites A, B, and C (MRID 00012039).

4. Mint hay (peppermint and spearmint)

Terbacil is applied to mint by ground* or by air** at 0.8-1.6 lb ai/A as a broadcast, preemergence weed treatment. One annual application is made in the spring or fall before new growth appears. Use is limited to the Midwest and the Pacific Northwest. A tolerance of 2 ppm has been established for combined residues of terbacil and Metabolites A, B, and C in or mint hay.

Peppermint hay, from field plots treated with terbacil at 1.6 or 2,4 lb ai/A with a detection limit at <.04 ppm, contained terbacil 46-241 days after treatment. Metabolites A, B, and C were not quantified. Peppermint oil, from mint grown in fields treated with terbacil at 0.8-2.4 lb ai/A, did not contain detectable terbacil residues (<0.04 ppm) (DuPont, MRIDs 00012103, 00390022).

---

* In at least 40 gallons of water/A
** In 5-10 gallons of water/A

Hay, from spearmint and peppermint treated in the field with terbacil 80% wettable powder at 1-2.1 lb ai/A, contained combined residues of terbacil and Metabolites A, B, and C at <1.53 ppm 42-135 days arter treatement. Oil from these plants contained combined residues of 0.48 ppm (DuPont, MRID 00012067).

Available data are adequate to support the 2.0 ppm tolerance for combined residues of terbacil and metabolites A, B, and C in or on mint hay because combined residues did exceed the tolerance after treatment at or above the maximum recommended rate. Mint oil derived from terbacil-treated plants also contained combined residue less than the tolerance for the raw commodity mint hay (DuPont, MRID 00012067).

5. Strawberries

Terbacil is applied to strawberries at 0.4-1.0 lb ai/A by ground equipment in all states except Florida. Single annual broadcast applications are made to dormant plants or postharvest after complete leaf removal. Terbacil should not be used on soils with less than 2% organic matter. The established tolerance for combined residues of terbacil and metabolites A, B, and C in or on strawberries is 0.1 ppm.

Strawberries, 2-12 months after treatment with terbacil 80% wettable powder at 0.8-4.0 lb ai/A, contained nondetectable levels (?0.04ppm) of terbacil and metabolites A, B, and C, except in 1 of 15 samples that contained a metabolite at 0.05 ppm (Rutgers University, MRID 00012097).

Available data are adequate to support the 0.1 ppm tolerance for combined residues of terbacil and Metabolites A, B, and C in or on strawberries.

6. Sainfoin (Forage and Hay)

The recommended terbacil application rates for alfalfa are 0.4-1.2 ai/A. A single ground application is to occur in the fall after cutting, or after plants become dormant or in the spring before new growth starts. There is a restriction against the application to seedling sainfoin or sainfoin grass mixtures or other mixed stands (DuPont, MRID 00011959).

Terbacil and the metabolites are determined by the same analytical method used for alfalfa. This method was tested by EPA on alfalfa hay at 1 ppm and 2 ppm. The results were favorable and the method was judged to be adequate for enforcement of tolerances on alfalfa hay (5 ppm). These results can be extended to include sainfoin.

No data are available for sainfoin forage or hay. Because the commodities alfalfa and sainfoin are similar and the terbacil treatments are the same for both, residues of terbacil in sainfoin are not likely to exceed the established 5 ppm tolerance.

7. Pecans

Terbacil is used as a weed killer in pecan groves with trees established for at least one year. A tank-mix use with diuron is also registered.

Terbacil is to be used alone as a band or broadcast application in a directed spray at rates of 1.6-2.4 lb. ai/A depending upon the soil texture. Application is to occur in the spring before weeds emerge or during early seedling stage of weed growth. Contact of the herbicide with nuts or foliage is to be avoided (DuPont, MRID 0039016).

A tank-mixture treatment is proposed under the above conditions at rates of 0.8-1.6 lb. ai/A terbacil plus 0.8-1.6 lb. a.i. diuron per acre.

The analytical method used for the collection of data is the same (with minor modifications) as that used for alfalfa which was successfully tried out in one of EPA's laboratories.

The results of the method tryout can be extended to include pecans and the analytical method indicated is adequate for the collection of residue data and for regulatory enforcement purposes.

Pecan samples were obtained from groves, in Florida, Georgia and Kansas, which had been treated with terbacil alone at rates of 1.6-4.0 lb. ai/A (1.7X maximum registered) and the tank-mix of terbacil plus diuron (1.6-3.2 + 1.6-3.2) lb. ai/A (2X registered rates).

No residues of terbacil or its metabolites or diuron were detected in nutmeats or pecans by a method sensitive to 0.05 ppm.

It is concluded that residues of terbacil and its metabolites in pecans are not likely to exceed the established tolerance (0.1 ppm) from the registered use.

Residues of diuron in or on pecans will be considered in the Registration Standard which is presently being generated for diuron.

8. Caneberries

For use as a weedkiller in caneberries (blackberries, boysenberries, dewberries, loganberries, raspberries, youngberries) terbacil is to be used at the rate of 0.8-1.6 lb. ai/A. A single application is to be made to the soil beneath the canes in the fall or early spring, before fruit set and before weeds emerge, or during the early stage of weed growth. The foliage is not to be sprayed. The herbicide is to be used only in established cane areas (at least one year). No application is to occur within 70 days before harvest (DuPont, MRID 00390015).

The analytical method used for the collection of residue data and/or regulatory enforcement purposes has been found satisfactory. Untreated sample of blackberries, boysenberries and raspberries showed no detectable (<0.04 ppm) residues of terbacil or its metabolites (DuPont, MRID 00390015).

Control samples of blackberries, boysenberries and raspberries were fortified with terbacil and its metabolites at levels of 0.04-0.4 ppm. Recoveries were generally 75-134%, but 3 aberrant values were noted: 48%, 150% and 160%.

Samples of blackberries, raspberries, and boysenberries were collected from treated fields in Oregon, Florida, Arkansas, Michigan and California. These had been treated at recommended rates of 1-6.4 lb. act/A (up to 4X the maximum registered rate).

The caneberries showed residues of less than 0.04 ppm (i.e., no detectable residues) from the treatment with a 49-day PHI (a 70-day PHI is recomended). Residues in all samples were non-detectable (0.04 ppm) at rates of 1-6.4 lb ai/A and PhIs of 58-124 days, except in one sample which was considered atypical.

The value of that sample (0.28 ppm) was one of 16, and is considered atypical because the recommended treatment was not followed.

No data were submitted for the by-products (juices, jellies, jams, preserves). However, the absence of detectable residues in the berries indicates that residues, if any, in these by-products are not likely to exceed the level in the berries.

Residues in caneberries are not likely to exceed the established tolerance (0.1 ppm).

9. Asparagus

For the use of terbacil on asparagus, the following rates of application are registered:

A single broadcast application of terbacil is to be made at a rate of 1.2 to 2.4 lbs. a.i./A to established asparagus. It is to be applied each season prior to spear emergence and at least seven days before harvest (DuPont, MRID 0002854).

For newly seeded asparagus, terbacil is applied at the rate of 0.8 to 1.6 lbs. a.i./A once a season. During the planting operation, a 1" band of activated charcoal is applied over the seed row followed by terbacil application.

Terbacil and its metabolites are determined by the analytical method of Holt and Pease (00011949 and 1977, 05015405).

Recoveries for terbacil and its metabolites in asparagus fortified at 0.06 ppm ranged from 80-95% for terbacil, 64-105% for metabolite A, 60-115% for metabolite B and 70-92% for metabolite C. The untreated samples did not exhibit residues greater than the sensitivity of the method (0.04 ppm).

The analytical method is adequate and sensitive enough for the enforcement of the established tolerance of 0.2 ppm.

Eleven residue tests were conducted in California, Delaware, Michighan, Missouri and New Jersey. Terbacil is known to be absorbed by plants but only when exaggerated rates (3-5 lbs. a.i./A) and/or shorter PHIs than recommended were used did the level of residue exceed the sensitivity of the method. When terbacil was applied at the registered rate and analyzed after a 7-day PHI, no residues were detected (analytical method sensitive 0.04 ppm). It is

concluded that the residue data support the established tolerance of 0.2 ppm for terbacil and its metabolites.

10. Apples, pears and peaches

Terbacil is to be used in established orchards for the control of a variety of weeds. A single application is to be made in the spring before emergence or during early growth of weeds. It is to be applied to the ground beneath and/or between the trees. The maximum use rate is 3.2 lbs. a.i./A.

Users are directed not to replant treated areas with any other crop within two years after treatment of apples, pears or peaches. Residues of terbacil alone were determined by an analytical method which was tried out on peaches and oranges in one the Agency's laboratories. Recoveries for terbacil using the Micro-Tek-220 GLC instrument were found to be 82-86% with peaches fortified at 0.2 ppm. It is estimated that this analytical method for terbacil is sensitive to at least 0.04 ppm. The method is considered adequate also for the determination of residues of terbacil in apples, pears and peaches.

Fifteen studies on apples included four varieties and locations in Michigan, Delaware, Pennsylvania and New Jersey. Timing, number and rates of application followed those stated on the registered label. Maximum dose applied was 8 lbs. ai/A (3.2 lbs. ai/A is the maximum recommended rate). The residue data for the apples show that no residues of terbacil greater than the method sensitivity were found (0.04 ppm) in any of the samples from the treated orchards. Minimum PHI was 123 days (Stauffer Chemical, MRID 00070784).

Three studies with two varieties of pears were conducted in Wasington. Data in these studies also reflected a maximum dose rate of 8 lbs. ai/A as compared to 3.2 lbs. ai/A maximum recommended rate. No residue above the method sensitivity (0.04 ppm) was found in any of the samples from the treated orchards. The PHI was 135 days in all the tests (DuPont, MRID 00012015).

Eight studies on peaches were conducted in South Carolina, California and Delaware. The data reflected application rates of up to 8 lbs. ai/A as compared to 3.2 lbs. ai/A maximum recommended rate. No residues above the method sensitivity (0.04 ppm) were found in any samples from the treated orchards. The minimum PHI was 72 days (DuPont, MRID 00012402).

The general pattern exhibited by the residue data is that no residues of terbacil in excess of the response of untreated check samples or the method sensitivity (0.04 ppm) were found present even at exaggerated rates of up to 2.5X. It is concluded that the established tolerances of 0.1 ppm for residues of terbacil in apples, pears and peaches are supported.

No data were given for dried apple pomace. However, even though residues may concentrate in converting to dried apply pomace, these residues are condidered unlikely to exceed the level (0.1 ppm) of the established tolerance.

11. Citrus

Terbacil is to be used for control of certain perennial grasses and annual weeds. The single application is to be made in the spring before weeds become

established. Terbacil is to be applied to the ground beneath and/or between the trees. The maximum use rate is 8 lbs. ai/A. The residues were determined by the same method mentioned under apples, pears and peaches. Recoveries at 0.04 to 5 ppm were found to be 86-110%. The sensitivity of the method with a 25-gram sample and determination of 1 microgram of terbacil is about 0.04 ppm, the same as for apples and pears (DuPont, MRID 00013205, 000122015).

For citrus, sixteen studies involving oranges, grapefruit, lemons and tangelos were conducted in Florida and Texas. These data reflected the conditions of use recommended on the label. The maximum rate of application was 16 lbs. ai/A (8 lbs. ai/A is the maximum recommended rate on the label) (California Citrus Research Center, MRID 00012232).

No residues above the method sensitivity (0.04 ppm) were found in any of the samples form the treated groves even at exaggerated rates up to 2X. The minimum PHI or terbacil was 235 days.

The established 0.1 ppm tolerance for residues of terbacil on citrus adequately covers the expected residues from the registered use.

No data were given for dried citrus pulp or citrus molasses; however, even though residue may concentrate in converting to dried citrus pulp, these residues are considered unlikely to exceed the level (0.1 ppm) of the established tolerance.

12. Residue in Meat and Milk

The major contributor of residues to the animal diet are alfalfa and sainfoin which constitute approximately 66% of the diet of cattle. Based on the 5 ppm combined residues of terbacil and metabolites A, B, and C in alfalfa and sainfoin, the maximum intake in the diet of cattle should be 3.3 ppm. This intake may amount to 4.0 ppm under conditions when alfalfa or sainfoin constitute as high as 80% of the animal diet.

It is concluded that residues will result in meat and milk of cattle from the feed use of alfalfa or sainfoin containing residues of terbacil and its metabolites A, B and C at 5 ppm. However, such residues are adequately covered by the existing tolerances of 0.1 ppm for meat, fat and meat by-products of cattle and 0.5 ppm for milk fat.

Two lactating Guernsey cows were fed terbacil at levels of 2 and 20 ppm for 32 days. The cow fed 2 pm of terbacil showed no dectable residues (0.04 ppm) in milk or any tissue, except that 0.05 ppm was found in the milk fat at the end of the feeding period. The cow fed 50 ppm showed a presence of terbacil at levels as high as 0.19 ppm and 0.07 ppm of metabolite A in whole milk, 0.64 ppm in mild fat, 0.07 ppm in skim milk, and 0.05 ppm in kidney tissue. Terbacil was not found in the liver, muscle, or fat of this cow (DuPont, MRID 000111963).

A latating Toggenburg nanny goat was fed [^{14}C]terbacil at 4.8 ppm for 5 days. There were no terbacil residues present (0.01 ppm) in fat, but levels were up to 0.05 ppm in milk, 0.07 ppm in liver, 0.14 ppm in kidney, and 0.01 ppm in three muscle tissues (Rhodes, MRID 00011957).

The feed use of sainfoin to hogs and poultry is not anticipated, but it is expected that it will be fed to goats, horses and sheep. Therefore, no residues from this source are expected in meat and eggs of poultry and in the meat of hogs, but those the residues which will result in the meat of goats, horses and sheep will be adequately covered by the existing tolerance of 0.1 ppm.

Residues of terbacil alone in dried citrus pulp, citrus molasses and dried apple pomace do not exceed 0.1 ppm. The feed use of these items should not contribute substantially to residues in meat and milk, relative to the contributions of alfalfa or sainfoin.

There is one source of substantial residues in meat and milk which has not been adequately covered, that is the cover crops. Such crops can contain residues. To avoid the ingestion of residues from this source, there is a restriction only against the grazing of livestock in treated pecan orchards. Restrictions of this kind are also needed in apple, pear and peach orchards and in citrus groves. This constitutes a label requirement.

With this restriction, the existing tolerances for residues in milk fat at 0.5 ppm (equivalent to whole milk at 0.1 ppm), and in meat, meat by-products and fat of cattle, goats, hogs and horses at 0.1 ppm will adequately cover the residues which may result from these uses of terbacil. This assumes, however, that residues of metabolites A, B and C in dried citrus pulp, citrus molasses, dried apple pomace and pecan shells are numerically insignificant (DuPont, 000111963; Rhodes, 1974, 00011957).

At a maximum dietary intake level of 3.3 ppm, the submitted residue data support the established tolerances 0.1 ppm for meat and milk of cattle, goats, sheep, horses and hogs.

13. Residues in Poultry and Eggs

White leghorn laying hens were fed terbacil at levels of 1 and 5 ppm for 28 days. No residues of terbacil or its metabolites were detected (<0.04 ppm) in meat or eggs (DuPont, MRID 00011945).

There are no current tolerances for poultry meat or eggs and none are needed at this time.

14. Section 24(c) Uses

Additional registrations for the use of terbacil on alfalfa, blueberries, and strawberries, and new uses on perennial grasses grown for seed (non-food use) were granted. All rates for the food or feed crops are identical to the federally registered uses. The only difference from the Federal label for alfalfa and blueberries is the option to apply terbacil aerially.

For strawberries, application cannot be made to soils containing less than 0.5% organic matter, whereas the Federal label sets the limt at 2% organic matter. Although no data are available to determine if the aerial application or organic matter content differences should result in higher terbacil

residues on treated crops than those associated with federally registered uses, it is reasonable to conclude that the registered Section 24(c) uses are in compliance with the respective established crop tolerances. This is supported by the lack of regulatory incidents reported by FDA.

F. Summary of Data Gaps

Should the existing tolerances for apples, citrus fruits, peaches, pears, and sugarcane be revised to include the metabolites A, B, and C, then additional metabolism and residue data areconditional on a change in the expression of the tolerance from terbacil alone to terbacil and metabolites A, B and C.

A general label restriction against the grazing or feeding of cover crops to livestock should be imposed.

Chapter VIII

Ecological Effects

A. Ecological Effects Profile

1. Non-Target Organisms

Sufficient information is available on the toxicity of terbacil to nontarget organisms to characterize technical terbacil as practically nontoxic to birds when administered through the diet. The LC_{50} is greater than 5,000 ppm in the mallard duck with technical terbacil. For the 80% formulated product, the LC_{50} is greater than 5,000 ppm in the mallard duck and equal to 26,426 ppm in the ring-necked pheasant. No data are available concerning the acute single-dose oral LD_{50} to birds.

Available data are adequate to characterize terbacil as relatively nontoxic to honeybees with an LD_{50} greater than 193 micrograms/bee.

Available data are sufficient to characterize technical terbacil as slightly toxic to freshwater aquatic invertebrates with an LC_{50} of 46.2 ppm and practically nontoxic to warm water fish with an LC_{50} of 102.9 ppm.

No data are available to determine the toxicity of technical terbacil to marine or estuarine fish.

A study on grass shrimp with an 84.7% formulated product was sufficient to characterize terbacil as slightly toxic to marine invertebrates, with an equivalent EC_{50} of 41 ppm if 100% active. Another study on the same product was only sufficient to characterize terbacil as no more than moderately toxic to oyster embryo larvae (EC^{50} >4.9 ppm).

B. Ecological Effects: Manufacturing-use Terbacil

1. Non-target Organisms

Birds

No data are available to determine the acute toxicity of terbacil to birds. An acute LD_{50} test should be performed on either the mallard duck or the ring-necked pheasant.

Three studies were evaluated on the dietary toxicity of terbacil to birds. Two studies were found valid and acceptable. One test performed on a wild waterfowl (the mallard duck) used a 96% a.i. formulation. The results characterized terbacil, with an LC_{50} greater than 5,000 ppm, as practically nontoxic to birds (Moore, MRID 00390020).

Another test performed on upland game bird (the ring-necked pheasant) used an 80% wettable powder formulation. The LC_{50} is equal to 26,426 ppm which is practically nontoxic to birds (Wazeter, Mrid 00012346).

Both studies characterize technical terbacil and the formulated product as practically nontoxic to birds.

Beneficial Insects

Although there are no guidelines requirements to evaluate the toxicity of pesticides to nontarget insects, one study on honeybees was evaluated and found acceptable under the Ammonium Sulfamate Registration Standard.

Honeybees were exposed to a mixture of technical terbacil and pyrolite dust. The result from this test characterize terbacil, with an LD_{50} greater than 193 micrograms/bee, as relatively nontoxic to honeybees (Atkins, MRID 00018842).

Freshwater Aquatic Invertebrates

One study was evaluated and found acceptable to determine the effects of terbacil to freshwater invertebrates. A 48-hour EC_{50} test used a 95% a.i. technical formulation on Daphnia magna. The results from this test characterize terbacil, with an LC_{50} of 65 ppm, as slightly toxic to freshwater aquatic invertebrates (McCann, MRID 00390018).

Freshwater Fish

Four 96-hour LC_{50} studies were evaluated and found acceptable to determine the effects of terbacil to freshwater fish. Two of these studies used a 96% technical formulation to establish an acute toxicity of terbacil to a cold water species (rainbow trout) and to a warm water species (bluegill sunfish).

The results of these test characterize terbacil, with an LC_{50} of 46.2 ppm, as slightly toxic to cold water fish (Smith, MRID 00390017); and, with an LC_{50} of 10.9 ppm, as practically nontoxic to warm water fish (Summers, MRID 00390019).

Estuarine and Marine Organisms

Terbacil may be expected to enter the estuarine or marine envoronment due to its extensive use as a sugarcane herbicide.

The minimum data required for establishing the acute toxicity of terbacil in estuarine or marine organism are the results from two 96-hour LD_{50} tests, one test performed on shrimp and one on an estuarine or marine fish, and the results from a 48-hour EC_{50} test for oyster embrylarvae or a 96-hour EC_{50} shell deposition test.

The results from a study on grass shrimp that used an 84.7% formulation of terbacil were sufficient to characterize terbacil as slightly toxic to marine invertebrates, with an EC_{50} equivalent to 41 ppm if 100% active (Bentley, MRID 00012332).

Since the degree of toxicity of the 84.7% formulation to grass shrimp is probably similar to the toxicity of the technical material, the requirement

for a 96-hour LC_{50} on shrimp is satisfied.

Another study on the same product was only sufficient to characterize terbacil as no more than moderately toxic to oyster embryolarvae (EC_{50} >4.9 ppm).

The requirement for an LC_{50} performed on a marine or estuarine fish and for an oyster acute test have not been satisfied and constitute a data gap. These two tests should be performed using technical terbacil.

Due to the mobility and environmental persistence of terbacil, chronic hazards to aquatic organisms are a concern. Pending additional environmental fate data, a chronic study performed on the sheephead minnow and a life-cycle test performed on the marine mysid shrimp may be requested.

C. Hazard Assessment

1. Nontarget Organisms

Seventy-five percent of the total domestic usage of terbacil is as a sugarcane herbicide. About half of the total sugarcane acreage in the United States is in Louisiana and Texas (c. 300,000 acres), the two states in which terbacil is currently registered. In Louisiana, the sugarcane growing area is contained within the Mississippi Delta region. In Texas, a much less extensive sugarcane growing area occurs in the southernmost tip of the state. The use of terbacil in these states may result in exposure to aquatic organisms, including marine and estuarine organisms. An additional 300,000 plus acres of sugarcane production are located in Florida, where the crop is restricted to the muck soils to the south and southeast of Lake Okeechobee. If the use of terbacil on sugarcane were expanded to include Florida, freshwater habitats and, to a lesser extent, marine and estuarine environments in that state may be exposed.

Terbacil is not expected to adversely affect avian species due to its lack of toxicity to these species.

D. Summary of Data Gaps

1. Nontarget Organisms

The major ecological effects data gaps for terbacil are the avian single-dose oral LD_{50} and the acute toxicity studies on estuarine and marine organims listed in the table in Chapter III.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Standard

005016657 Andersen, K.J.; Leighty, E.G.; Takahashi, M.T. (1972) Evaluation of herbicides for possible mutagenic properties. Journal of Agricultural and Food Chemistry 20(3):649-656.

000018842 Atkins, E.L., Jr.; Anderson, L.D.; Greywood, E.A. (1969) Effect of Pesticides on Agriculture: Project No. 1499; Research Report CF-7501. (Unpublished study received May 8, 1971 under 1F1174; prepared by Univ. of California--Riverside, Dept. of Entomology, submitted by Ciba Agrochemical Co., Summit, N.J.; CDL:090973-B)

005020698 Benson, N.R. (1973) Efficacy, Leaching, and Persistence of Herbicides in Apple Orchards. Pullman, Wash.: Washington State University, College of Agriculture Research Center. (Washington State University, College of Agriculture Research Center, bulletin no. 863)

000012332 Bentley, R.E. (1973) Bioassay Report Submitted to E.I. du Pont de Nemours & Co.: Sinbar Terbacil Weed Killer, 80% Wettable Powder: Acute Toxicity of H-8309 to Grass Shrimp (Palaemonetes vulgaris) and Fiddler Crab (Uca pugilator). (Unpublished study received Apr 11, 1974 under 352-17; prepared by Bionomics, Inc., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:129203-B)

005013352 Cessna, A.J. (1977) Determination of terbacil in blueberries. Journal of Agricultural and Food Chemistry 25(2):432-433.

005014424 Davidson, J.M.; Ou, L.T.; Rao, P.S.C. (1978) Adsorption, movement, and biological degradation of high concentrations of selected pesticides in soils. Pages 233-244, In Land Disposal of Hazardous Wastes. Washington, D.C.: U.S. Environmental Protection Agency, Office of Research and Development. (EPA-600/9-78-016)

005013351 Doughty, C.C. (1978) Terbacil phytotoxicity and quackgrass (Agropyron repens) control in highbush blueberries (Vaccinium corymbosum). Weed Science 26(5):448-492.

000011945 E.I. du Pont de Nemours & Company (19??) Terbacil: Poultry Feeding Study: Residue Data-Tissues and Eggs. (Unpublished study received on unknown date under 4F1428; CDL:098172-A)

000012067 E.I. du Pont de Nemours & Company (1975) Results of Tests on the Amount of Residue Remaining on Treated Crops: [Terbacil]. (Unpublished study received Dec 3, 1975 under 4F1428; CDL:095184-C)

000011948 E.I. du Pont de Nemours & Company (1975) Terbacil--Rotational Crop Studies. (Unpublished study received Nov 25, 1975 under 4F1428; CDL:094842-C)

000012348 E.I. du Pont de Nemours & Company (1977) Results of Tests on the Amount of Residue Remaining on Treated Crops: [Terbacil]. (Unpublished study received Jan 11, 1978 under 352-317; CDL:096709-D)

000026948 E.I. du Pont de Nemours & Company (1977) Terbacil/Shelled Pecans--Representative Chromatograms. (Unpublished study received Jan 11, 1978 under 352-317; CDL:096709-U)

000011961 E.I. du Pont de Nemours & Company, Incorporated (19??) Determination of Terbacil and Its Metabolites in Milk and Urine. (Unpublished study received Aug 30, 1973 under 4F1428; CDL:093806-D)

000012365 E.I. du Pont de Nemours & Company, Incorporated (19??) Sinbar Terbacil Weed Killer: Determination of Terbacil and 3-tert-Butyl-6-methyluracil: High-Performance Liquid Chromatographic Method. (Unpublished study received Nov 7, 1978 under 352-317; CDL:235690-B)

000012364 E.I. du Pont de Nemours and Company (19??) Composition of Technical Terbacil: Active Ingredient in Sinbar Weed Killer. (Unpublished study received Nov 7, 1978 under 352-317; CDL:235690-A)

000012366 E.I. du Pont de Nemours and Company (19??) Purity of Starting and Intermediate Materials Used in the Terbacil Manufacturing Process. (Unpublished study received Nov 7, 1978 under 352-317; CDL:235690-C)

000012103 E.I. du Pont de Nemours and Company (1966) Results of Tests on the Amount of Residue on Crops Grown on Treated Soil: [Terbacil]. (Unpublished study received Nov 16, 1966 under 7F0549; CDL:092838-B)

000012180 E.I. du Pont de Nemours and Company (1966) Sinbar Weed Killer (3-tert-Butyl-5-chloro-6-methyluracil) Residue Data--Sugar Cane. (Unpublished study received Feb 9, 1966 under unknown admin. no.; CDL:124200-A)

000012179 E.I. du Pont de Nemours and Company (1966) Sinbar Weed Killer Residue Data--Sugar Cane: Supplemental Information. (Unpublished study received Apr 13, 1966 under unknown admin. no.; CDL:124198-A)

000011963 E.I. du Pont de Nemours and Company (1968?) Terbacil: Livestock Feeding Study--Milk and Meat. (Unpublished study received Aug 30, 1973 under 4F14287; CDL:093806-G)

000011958 E.I. du Pont de Nemours and Company (1973) Name, Chemical Identity, and Composition: [Terbacil]. (Unpublished study received Aug 30, 1973 under 4F1428; CDL:093806-A)

000011959 E.I. du Pont de Nemours and Company (1973) Results of Tests on the Amount of Residue Remaining on Treated Crops: [Terbacil]. Summary of studies 093806-C through 093806-L. (Unpublished study received Aug 30, 1973 under 4F1428; CDL:093806-B)

000011954 E.I. du Pont de Nemours and Company (1974) Du Pont Trade Secret Information: Manufacturing Process for Terbacil. (Unpublished study received Oct 1, 1974 under 4F1428; CDL:093805-G)

000012032 Gardiner, J.A. (19??) Analysis of the Urine of Terbacil-Fed Dogs for the Presence of 5-Chlorouracil. (Unpublished study received Dec 2, 1966 under 6F0510; submitted by E.I. du Pont de Nemours & Co., Inc.; Wilmington, Del.; CDL:092796-F)

000012031 Gardiner, J.A. (19??) Examination of 14C-Terbacil-Treated Soil for the Possible Presence of 5-Chlorouracil. (Unpublished study received Dec 2, 1966 under 6F0510; submitted by E.I. du Pont de Nemours & Co., Inc.; Wilmington, Del.; CDL:092796-G)

000012032 Gardiner, J.A. (19??) Exposure of 2-14C-Labeled Terbacil to Field Conditions: Supplement I. (Unpublished study received Dec 2, 1966 under 6F0510; submitted by E.I. du Pont de Nemours & Co., Inc.; Wilmington, Del.; CDL:092796-H)

000012208 Gardiner, J.A. (1964?) Laboratory Exposure of 2-14C-Labeled Terbacil to Moisture, Light, and Nonsterile Soil. (Unpublished study received Jan 20, 1965 under 352-317; submitted by E.I. du Pont de Nemours & Co., Inc.; Wilmington, Del.; CDL:100232-D)

005002415 Gardiner, J.A.; Rhodes, R.C.; Adams, J.B., Jr.; Soboczenski, E.J. (1969) Synthesis and studies with 2-C14-labeled bromacil and terbacil. Journal of Agricultural and Food Chemistry 17(5):980-936.

005002373 Gutenmann, W.H.; Lisk, D.J. (1969) Excretory pathway of Terbacil (Sinbar) in lactating cows. Journal of Agricultural and Food Chemistry 17(5):1011-1013.

000011950 Han, J.C. (1973?) 2-14C-Terbacil Goat Metabolism Study. (Unpublished study received Oct 1, 1974 under 4F1428; submitted by E.I. du Pont de Nemours & Co., Inc.; Wilmington, Del.; CDL:093805-B)

000011960 Holt, R.F.; Pease, H.L. (1971?) Residue Procedure for the Determination of Terbacil and Its Metabolites in Alfalfa. Undated method. (Unpublished study received Aug 30, 1973 under 4F1428; submitted by E.I. du Pont de Nemours & Co., Inc.; Wilmington, Del.; CDL:093806-C)

000011949 Holt, R.F.; Pease, H.L. (1971?) Residue Procedure for the Determination of Terbacil and Its Metabolites Using Microcoulometric Gas Chromatography. Undated method. (Unpublished study received Nov 25, 1975 under 4F1428; submitted by E.I. du Pont de Nemours & Co., Inc.; Wilmington, Del.; CDL:094842-D)

005015405 Holt, R.F.; Pease, H.L. (1977) Determination of terbacil and metabolite residues using microcoulometric gas chromatography. Journal of Agricultural and Food Chemistry 25(2):373-377.

000012097 IR-4 Project at Rutgers, the State University (1972) Analytical Residues: [Terbacil]. (Unpublished study received Mar 14, 1977 under 7E1936; CDL:097354-A)

000012039 IR-4 Project at Rutgers, the State University (1973) Results of Tests on the Amount of Residue Remaining on Treated Blueberries:

000028135 Isom, W.H.; Ford, H.P.; Lavalleye, M.P.; et al. (1969) Persistence

005019594 Isom, W.H.; Ford, H.P.; Lavalleye, M.P.; Jordan, L.S. (1970) Persistence of herbicides in irrigated soils. Pages 58-63, In Proceedings of the Annual California Weed Conference. Vol. 22. Sacramento, Calif.: California Weed Conference.

005013598 Jordan, L.S.; Zurgiyah, A.A.; Clerx,W.A.; Leash, J.G. (1975) Metabolism of terbacil in orange seedlings. Archives of Environmental Contamination and Toxicology 3(3):263-277.

005014175 Liu, L.C.; Cibes-Viade, H.; Koo, F.K.S. (1971) Adsorption of Atrazine and Terbacil by soils. Journal of Agriculture of the University of Puerto Rico 55(4):451-460.

005015406 Liu, L.C.; Cibes-Viade, H.R. (1972) Effect of various herbicides on the respiration of soil microorganisms. Journal of Agriculture of the University of Puerto Rico 56(4):417-425.

000017711 Liu, L.C.; Cibes-Viade, H.R.; Gonzalez-Ibanez, J. (19??) Persistence of several herbicides in soil cropped to sugarcane. Journal of Agriculture of the University of Puerto Rico ( ):147-152. (Also In unpublished submission received Aug 20, 1976 under 39445-1; submitted by American Carbonyl, Inc., Tenafly, N.J.; CDL:228229-Y)

005014421 Mansell, R.S.; Calvert, D.V.; Stewart, E.H.; Wheeler, W.B.; Rogers, J.S.; Graetz, D.A.; Allen, L.H.; Overman, A.R.; Knipling, E.B. (1977) Fertilizer and Pesticide Movement from Citrus Groves in Florida Flatwood Soils. Athens, Ga.: U.S. Environmental Protection Agency, Environmental Research Laboratory. (EPA-600/2-77-177; available from: NTIS, Springfield, VA; PB-272 889)

005017062 Mansell, R.S.; Wheeler, W.B.; Calvert, D.V.; Stewart, E.H. (1979) Terbacil movement in drainage waters from a citrus grove in a Florida flatwood soil. Pages 176-179, In Proceedings of the Soil and Crop Science Society of Florida; 1978. Vol. 37. De Land, Fla.: Soil and Crop Science Society of Florida. (Florida Agricultural Experiment Stations journal series no. 1053)

000390010 E.I. du Pont de Nemours and Company (1980) Oral Teratology Study in Rats (481-79)

000390015 Holt, R., Pease (1977) Residue Data - Dupont Sinbar Weed Killer/Small Fruits (Blackberries, Raspberries and Boysenberries) Determination of Terbacil and Metabolite Residues Using Microcoulometric Gas Chromatography

000390001 International Research and Development Corporation (1967) Chronic Feeding and Oncogenicity Study in Rats (125-010)

000390002 International Research and Development Corporation (1967) Two-Year Chronic Feeding Study in Dogs (125-011)

000390003 International Research and Development Corporation (1967) Three-Generation Reproduction Study in Rats (125-012)

000028524 International Research Project Number 4 (1976) Terbacil Residue Data Summary: Asparagus. (Unpublished study received June 11, 1980 under E2371; CDL:099449-A)

000390018 McCann, J. A. (1981) Static Jar Test No. 2747, Daphnia magna Terrestrial and Aquatic Biology Unit, USEPA, Beltsville, MD.

000390020 Moore, S. C. (1979) Avian Dietary Toxicity (LC_{50} Study in Mallard Duck H-12, 547-02 Final Report. Hazleton Laboratories, Inc., CDL:241146)

000390023 Pease, H. L. (1974) Verification of the Residue Method for Terbacil and its Metabolites (Unpublished Report #1235)

000390017 Smith, E. J., C. F. Muska, and R. W. Hartgrove, Jr. (1980) 96-hour LC_{50} to Rainbow Trout. Haskell Laboratory Report No. 9-80. MR No. 0581-783

000070784 Stauffer Chemical Company (1980) Devrinol 50% WP Selective Herbicide: Summary of Crop Residue Data on Apples, Peaches, and Citrus. (Compilation; unpublished study received Dec 11, 1980 under 476-2108; CDL:243859-A).

000390019 Summers, J. C. (1978) 96-hour LC_{50} to Bluegill Sunfish (Lepomis Macrochirus) Report No. 701-78, Sample No. 12,547 (Submitted under EPA Reg. No. 352-317; CDL:241146)

005017061 Mansell, R.S.; Wheeler, W.B.; Elliott, L.; Shaurette, M. (1972) Movement of Acarol and Terbacil pesticides during displacement through columns of Wabasso fine sand. Pages 239-243, In Proceedings of the Soil and Crop Science Society of Florida; 1971. Vol. 31. Deland, Fla.: Soil and Crop Science Society of Florida. (Florida Agricultural Experiment Stations journal series no. 4368)

005013202 Marriage, P.B.; Khan, S.U.; Saidak, W.J. (1977) Persistence and movement of terbacil in peach orchard soil after repeated annual applications. Weed Research 17(3):219-225.

005013201 Marsh, J.A.P.; Davies, H.A. (1978) The effect of herbicides on respiration and transformation of nitrogen in two soils: III. Lenacil, terbacil, chlorthiamid and 2,4,5-T. Weed Research 18(1):57-62.

000013309 McGahen, J.W.; Hoffmann, C.E. (1965) Absence of Mutagenic Effects of 3- and 6-Alkyl-5-bromouracil Herbicides on a Bacteriophage. (Unpublished study received Nov 1, 1965 under unknown admin. no.; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:107587-A)

005013593 Morrow, L.A.; McCarty, M.K. (1976) Selectivity and soil persistence of certain herbicides used on perennial forage grasses. Journal of Environmental Quality 5(4):462-465.

005017208 Murnik, M.R. (1976) Mutagenicity of widely used herbicides

000012181 Pease, H.L. (19??) The Determination of Herbicide 732 Residues in Citrus. Undated method. (Unpublished study received Feb 9, 1966 under unknown admin. no.; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:124200-B)

000012035 Pease, H.L. (1964?) Determination of Terbacil Residues. Undated method. (Unpublished study received Jun 30, 1966 under 6F0510; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:092796-K)

000012979 Pease, H.L. (1968) Determination of terbacil residues using microcoulometric gas chromatography. Journal of Agricultural and Food Chemistry 16(1):54-56.

000011953 Pease, H.L. (1971?) Confirmatory Procedure for Residues of Terbacil and Its Metabolites. (Unpublished study received Oct 1, 1974 under 4F1428; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:093805-F)

005014422 Pease, H.L.; Leitch, R.E.; Hunt, O.R. (1978) Terbacil. Pages 483-492, In Analytical Methods for Pesticides and Plant Growth Regulators and Food Additives. Vol. 10. Edited by G. Zweig and J. Sherma. New York: Academic Press.

005013219 Rahman, A. (1977) Persistence of terbacil and trifluralin under different soil and climatic conditions. Weed Research 17 (2):145-152.

005008371 Roa, P.S.C., and J.M. Davidson. 1979. Adsorption and movement of selected pesticides at high concentrations in soils. Water Res. 13(4):375-380.

005013602 Ratnayake, M.; Audus, L.J. (1978) Studies on the effect of herbicides on soil nitrification, II. Pesticide Biochemistry and Physiology 8(2):170-185.

000011965 Rhodes, R.C. (1964?) Studies with 14C-Labeled Terbacil in Alfalfa. (Unpublished study received Aug 30, 1973 under 4F1428; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:093806-J)

000011947 Rhodes, R.C. (1969?) Four-Week Residue Studies with 2-14C-Terbacil and Bluegill Sunfish. (Unpublished study received Nov 25, 1975 under 4F1428; prepared in cooperation with Cannon Laboratories, Inc., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:094842-B)

000011957 Rhodes, R.C. (1974?) Five-Dose 2-14C-Terbacil Goat Study-Residue Analysis of Meat and Milk. (Unpublished study received Apr 25, 1975 under 4F1428; submitted by E.I, du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:094842-A)

000011946 Rhodes, R.C. (1975) Biodegradation Studies with 2-14C-Terbacil in Water and Soil. (Unpublished study received Nov 25, 1975 under 4F1428; prepared in cooperation with Univ. of Delaware, College of Agricultural Sciences, submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:094842-A)

005013216 Rhodes, R.C. (1977) Metabolism of [2-14C]terbacil in alfalfa. Journal of Agricultural and Food Chemistry 25(5):1066-1068.

000012014 Rhodes, R.C.; Weed, M.B. (19??) Distribution of 2-14C-Labeled Terbacil in Sugar Cane Following Injection. (Unpublished study received Dec 13, 1966 under 6F0510; submitted by E.I, du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:090603-M)

000012235 Sherman, H. (1965) Oral LD_{50} Test: Haskell Laboratory Report No. 160-65. (Unpublished study including letter dated Mar 2, 1966 from D.E. Rosen to J.S. Leary, received Mar 3, 1966 under 352-317; submitted by E.I, du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:100228-E)

005013212 Skroch, W.A.; Sheets, T.J.; Smith, J.W. (1971) Herbicide effectiveness, soil residues, and phytotoxicity to peach trees. Weed Science 19(3):257-260.

005018549 Thomas, V.M., Jr.; Buckley, L.J.; Sullivan, J.D., Jr.; Ikawa, M. (1973) Effect of herbicides on the growth of Chlorella and Bacillus using the paper disc method. Weed Science 21(5):449-451.

005017207 Tucker, D.P.; Phillips, R.L. (1970) Movement and degradation of herbicides in Florida citrus soil. Citrus Industry 51(3):11-13.

000012347 Wazeter, F.X.; Buller, R.H.; Geil, R.G. (1966) Acute Toxicity in Wildfowl (Pekin Duckling). (Unpublished study received on Jan 11, 1978 under 352-317; prepared by International Research and Development Corp., submitted by E.I, du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:096709-C)

000012346 Wazeter, F.X.; Buller, R.H.; Geil, R.G. (1966) Acute Toxicity in Wildfowl (Pheasant Chick). (Unpublished study received on Jan 11, 1978 under 352-317; prepared by International Research and Development Corp., submitted by E.I, du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:096709-B)

005015407 Wehr, N.B.; Klein, D.A. (1971) Herbicide effects on Bdellovibrio bacteriovorus parasitism of a soil pseudomonad. Soil Biology and Biochemistry 3(2):143-149.

005013194 Weierich, A.J.; Nelson, A.Z.; Appleby, A.P. (1977) Influence of fonofos on the distribution and metabolism of 14C-terbacil in peppermint. Weed Science 25(1):27-29.

005013204 Wolf, D.C. (1974) Degradation of bromacil, terbacil, 2,4-D and atrazine in soil and pure culture and their effect on microbial activity. Dissertation Abstracts International B 34(10):4783-4784.

005016176 Wolf, D.C.; Martin, J.P. (1974) Microbial degradation of 2-carbon-14 bromacil and terbacil. Proceedings of the Soil Science Society of America 38(6):921-925.

000024336 Wolf, D.C. 1973. Degradation of bromacil, terbacil, 2,4-D and atrazine in soil and pure culture and their effect on microbial activity. Ph.D. Dissertation, University of California, Riverside.

005012990 Zimdahl, R.L., V.H. Freed, M.L. Montgomery, and W.R. Furtick. 1970. The degradation of triazine and uracil herbicides in soil. Weed Res. 19:18-26.

000390011 Archer, A. J., S. Saltzman, N. Bates, and E. Dunkelblum (1981) Photosensitized Decomposition of Terbacil in Aqueous Solutions. J. Agric. Food Chem. [29(4):707-711]

000012232 California Citrus Research Center (1966) Residue Data: Terbacil--Citrus. (Unpublished study received Feb 16, 1967 under 352-317; submitted by E.I. du Pont de Nemours and Co., Wilmington, Del.; CDL:002958-M)

000390021 E.I. du Pont de Nemours and Company (19??) Recovery Data: Terbacil/Metabolites - Tissues Exhibit 2 (Unpublished Report #1237)

000390005 E.I. du Pont de Nemours and Company (1964) Ten-Dose Oral Subchronic Toxicity Study in Rats 8126-64

000390006 E.I. du Pont de Nemours and Company (1964) Primary Eye Irritation Study in Rabbits

000390007 E.I. du Pont de Nemours and Company (1965) Dermal Irritation and Sensitization Study in Albino Guinea Pigs.

000012015 E.I. du Pont de Nemours and Company (1966) Results of Tests on the Amount of Residue in Crops Grown on Treated Soil. (Unpublished study received Dec 13, 1966 under 6F0510; CDL:090603-)

000012015 E.I. du Pont de Nemours and Company (1966) Results of Tests on the Amount of Residue in Crops Grown on Treated Soil. (Unpublished study received Dec 13, 1966 under 6F0510; CDL:090603-)

000390022 E.I. du Pont de Nemours and Company (1966) Results of Tests on the Amount of Residue in Crops Grown on Treated Soil. Raw Agricultural Commodity - Mint Hay (Unpublished Report #1236)

000012402 E.I. du Pont de Nemours and Company (1973) Data Supporting the Use of Zobar I Weed Killer in Established Apples and Peaches. Summary of Studies 026721-B through 026721-Y. (Unpublished study received Oct 17, 1973 under 352-374; CDL:026721-A)

000390016 E.I. du Pont de Nemours and Company (1977) Results of Tests on the Amount of Residue Remaining on Treated Crops. (Submitted under Pesticide Petition 8E2084: Residue Tolerance of Terbacil on Pecans)